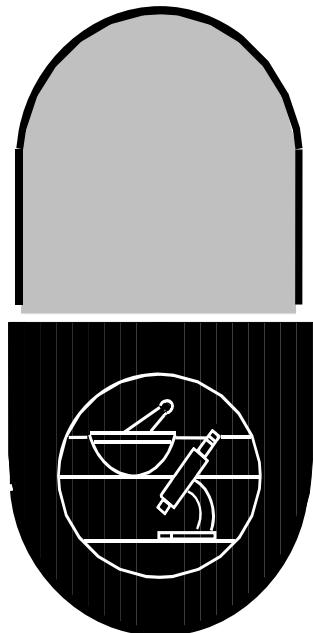


**CUMULATIVE
SUPPLEMENT 06
June 2008**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

28th EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

Prepared By
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

28th EDITION

Cumulative Supplement 06

June 2008

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

28th EDITION

**CUMULATIVE SUPPLEMENT 06
June 2008**

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 28th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 27th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 28th Edition. The current edition

Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity List new additions are indicated by the symbol >A> to the left of Patent Number or Exclusivity Code. The >A> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

1.2 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month's second work week (e.g., November's supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
 - o Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
 - o Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.
- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@cder.fda.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7500 Standish Place
Rockville, MD 20855-2773

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

| <u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u> |
|--|--|
| ABRIKA PHARMACEUTICALS LLP (ABRIKA PHARMS) | ACTAVIS SOUTHLANTIC LLC (ACTAVIS) |
| BRISTOL MYERS SQUIBB MEDICAL IMAGING (BRISTOL MYERS SQUIBB) | LANTHEUS MEDICAL IMAGING INC (LANTHEUS MEDCL) |
| CIS US INC (CIS) | PHARMALUCENCE INC (PHARMALUCENCE) |
| CONNETICS CORP (CONNETICS) | STIEFEL LABORATORIES INC (STIEFEL LABS INC) |
| GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMA) | GLENMARK GENERICS INC USA (GLENMARK GENERICS) |
| GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMS INC) | GLENMARK GENERICS LTD (GLENMARK GENERICS) |

| | |
|---|--|
| GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMA) | GLENMARK GENERICS LTD (GLENMARK GENERICS) |
| GLENMARK PHARMACEUTICALS LTD (GLENMARK PHARMS) | GLENMARK GENERICS INC USA (GLENMARK GENERICS) |
| GLENMARK PHARMACEUTICALS LTD (GLENMARK PHARMS) | GLENMARK GENERICS LTD (GLENMARK GENERICS) |
| GLENMARK PHARMACEUTICALS LTD INDIA (GLENMARK PHARMS LTD) | GLENMARK GENERICS LTD (GLENMARK GENERICS) |
| RELIANT PHARMACEUTICALS LLC (RELIANT PHARMS) | SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE (SMITHKLINE BEECHAM) |

1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.fda.gov/cder/ob/default.htm>, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Annual Edition. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: <http://bookstore.gpo.gov>; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/cder/rxotcdpl/pdplarchive.htm>

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are provided in eobzip.exe and eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly. Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *955-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts

are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2007) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST COUNTS CUMULATIVE BY QUARTER

| CATEGORIES COUNTED | DEC 2007 | MAR 2008 | JUN 2008 | SEPT 2008 |
|-------------------------|----------|----------|----------|-----------|
| DRUG PRODUCTS LISTED | 12302 | 12459 | 12622 | |
| SINGLE SOURCE | 2489 | 2514 | 2445 | |
| | (20.2%) | (20.2%) | (19.4%) | |
| MULTISOURCE | 9724 | 9856 | 10088 | |
| | (79.0%) | (79.1%) | (79.9%) | |
| THERAPEUTICALLY | 9571 | 9703 | 9924 | |
| EQUIVALENT | (77.8%) | (77.9%) | (78.6%) | |
| NOT THERAPEUTICALLY | 153 | 153 | 164 | |
| EQUIVALENT | (1.2%) | (1.2%) | (1.3%) | |
| EXCEPTIONS ¹ | 89 | 89 | 89 | |
| | (0.7%) | (0.7%) | (0.7%) | |
| NEW MOLECULAR ENTITIES | | | | |
| APPROVED | 7 | 7 | 6 | |
| NUMBER OF APPLICANTS | 693 | 710 | 709 | |

¹Amino acid-containing products of varying composition (see Introduction, page xx of the List).

1.6 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two columns describe the action. The Action Month is the CS

month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be proceeded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

| | |
|------|---|
| NEWA | New drug product approval usually in the supplement month. |
| CAHN | Applicant holder firm name has changed. |
| CAIN | Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name. |
| CDFR | Change. Dosage Form; Route of Administration. |
| CFTG | Change. A first time generic for the innovator product. A TE Code is added. |
| CMFD | Change. The product is moved from the Discontinued Section due to a change in marketing status. |
| CMS1 | Change. Miscellaneous addition to list. |
| CMS2 | Change. Miscellaneous deletion from list. |
| CPOT | Change. Potency amount/unit. |
| CRLD | Change. Reference Listed Drug. |
| CTEC | Change. Therapeutic Equivalence Code. |
| CTNA | Change. Trade Name. |
| DISC | Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition. |

PRESCRIPTION DRUG PRODUCT LIST - 28TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

1-1

ACARBOSE

TABLET; ORAL

ACARBOSE

| | | | | | | | | |
|-----|-----------------|----------------|--------|--------|--------------|--------------|------|------|
| AB | COBALT LABS INC | 25MG | N77532 | 001 | May 07, 2008 | Apr | NEWA | |
| AB | | 50MG | N77532 | 002 | May 07, 2008 | Apr | NEWA | |
| AB | | 100MG | N77532 | 003 | May 07, 2008 | Apr | NEWA | |
| AB | ROXANE | 25MG | N78470 | 001 | May 07, 2008 | Apr | NEWA | |
| AB | | 50MG | N78470 | 002 | May 07, 2008 | Apr | NEWA | |
| AB | | 100MG | N78470 | 003 | May 07, 2008 | Apr | NEWA | |
| | PRECOSE | | | | | | | |
| >A> | AB | BAYER HLTHCARE | 25MG | N20482 | 004 | May 29, 1997 | Jun | CAHN |
| >A> | AB | | 50MG | N20482 | 001 | Sep 06, 1995 | Jun | CAHN |
| >A> | AB | | 100MG | N20482 | 002 | Sep 06, 1995 | Jun | CAHN |
| >D> | AB | BAYER PHARMS | 25MG | N20482 | 004 | May 29, 1997 | Jun | CAHN |
| | AB | | 25MG | N20482 | 004 | May 29, 1997 | Apr | CFTG |
| >D> | AB | | 50MG | N20482 | 001 | Sep 06, 1995 | Jun | CAHN |
| | AB | | 50MG | N20482 | 001 | Sep 06, 1995 | Apr | CFTG |
| >D> | AB | | 100MG | N20482 | 002 | Sep 06, 1995 | Jun | CAHN |
| | AB | | 100MG | N20482 | 002 | Sep 06, 1995 | Apr | CFTG |

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL

ACEBUTOLOL HYDROCHLORIDE

| | | | | | | | |
|----|--------------|---------------|--------|-----|--------------|-----|------|
| AB | AMNEAL PHARM | EQ 200MG BASE | N75047 | 001 | Dec 30, 1999 | Feb | CAHN |
| AB | | EQ 400MG BASE | N75047 | 002 | Dec 30, 1999 | Feb | CAHN |

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

DHC PLUS

@ PHARM RES ASSOC 356.4MG;30MG;16MG

N88584 001 Mar 04, 1986 May CAHN

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL

ACETAMINOPHEN W/ CODEINE

| | | | | | | | |
|-----|----|--------|--------------------|--------|-----|-----|------|
| >D> | AA | ROXANE | 120MG/5ML;12MG/5ML | N86366 | 001 | Jun | DISC |
| >A> | @ | | 120MG/5ML;12MG/5ML | N86366 | 001 | Jun | DISC |

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

| | | | | | | | |
|----|----------------|------------|--------|-----|--------------|-----|------|
| AA | INTERPHARM | 300MG;30MG | N40779 | 001 | May 29, 2008 | May | NEWA |
| | @ MUTUAL PHARM | 300MG;15MG | N89671 | 001 | Feb 10, 1988 | Feb | DISC |

TYLENOL W/ CODEINE NO. 1

| | | | | | | |
|-----|------------------------|-------------|--------|-----|-----|------|
| >A> | @ ORTHO MCNEIL JANSSEN | 300MG;7.5MG | N85055 | 001 | Jun | CAHN |
| >D> | @ ORTHO MCNEIL PHARM | 300MG;7.5MG | N85055 | 001 | Jun | CAHN |

TYLENOL W/ CODEINE NO. 2

| | | | | | | |
|-----|------------------------|------------|--------|-----|-----|------|
| >A> | @ ORTHO MCNEIL JANSSEN | 300MG;15MG | N85055 | 002 | Jun | CAHN |
| >D> | @ ORTHO MCNEIL PHARM | 300MG;15MG | N85055 | 002 | Jun | CAHN |

TYLENOL W/ CODEINE NO. 3

| | | | | | | |
|-----|---------------------------|------------|--------|-----|-----|------|
| >A> | AA + ORTHO MCNEIL JANSSEN | 300MG;30MG | N85055 | 003 | Jun | CAHN |
| >D> | AA + ORTHO MCNEIL PHARM | 300MG;30MG | N85055 | 003 | Jun | CAHN |

TYLENOL W/ CODEINE NO. 4

| | | | | | | |
|-----|------------------------|------------|--------|-----|-----|------|
| >A> | @ ORTHO MCNEIL JANSSEN | 300MG;60MG | N85055 | 004 | Jun | CAHN |
| >D> | @ ORTHO MCNEIL PHARM | 300MG;60MG | N85055 | 004 | Jun | CAHN |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
 @ MIKART 500MG/15ML;5MG/15ML
 + PHARM ASSOC 325MG/15ML;10MG/15ML

N89557 001 Apr 29, 1992 Feb DISC
 N40834 001 Apr 18, 2008 Apr NEWA

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

TYLOX

>A> AA + ORTHO MCNEIL JANSSEN 500MG;5MG
 >D> AA + ORTHO MCNEIL PHARM 500MG;5MG

N88790 001 Dec 12, 1984 Jun CAHN
 N88790 001 Dec 12, 1984 Jun CAHN

TABLET; ORAL

PERCOSET

AA + ENDO PHARMS 325MG;5MG
 @ 325MG;5MG

N40330 002 Jun 25, 1999 Feb CRLD
 N85106 002 Feb DISC

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
 AB CONCORD LABS NJ 650MG;100MG

N77821 001 Feb 11, 2008 Jan NEWA

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE

TABLET; ORAL

ULTRACET

>A> AB + ORTHO MCNEIL JANSSEN 325MG;37.5MG
 >D> AB + ORTHO MCNEIL PHARM 325MG;37.5MG

N21123 001 Aug 15, 2001 Jun CAHN
 N21123 001 Aug 15, 2001 Jun CAHN

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

@ BARR 250MG
 @ 500MG
 WATSON LABS 250MG
 + 500MG

N70869 001 Feb 09, 1987 Feb DISC
 N70870 001 Feb 09, 1987 Jan DISC
 N71893 001 Nov 25, 1987 Feb CTEC
 N71894 001 Nov 25, 1987 Jan CRLD

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

@ APOTHECON 200MG
 TABLET; ORAL
 ACYCLOVIR
 @ APOTHECON 400MG
 @ 800MG

N74889 001 Oct 31, 1997 Feb DISC
 N74891 001 Oct 31, 1997 Feb DISC
 N74891 002 Oct 31, 1997 Feb DISC

ALBUTEROL SULFATE

AEROSOL, METERED; INHALATION

PROAIR HFA

>D> BX + IVAX RES LLC EQ 0.09MG BASE/INH
 >A> BX + TEVA GLOBAL EQ 0.09MG BASE/INH

N21457 001 Oct 29, 2004 Jun CAHN
 N21457 001 Oct 29, 2004 Jun CAHN

SYRUP; ORAL

ALBUTEROL SULFATE
 @ ACTAVIS MID ATLANTIC EQ 2MG BASE/5ML

N75262 001 Mar 30, 1999 Feb DISC

TABLET; ORAL

ALBUTEROL SULFATE

@ WATSON LABS EQ 4MG BASE

N72630 001 Jan 31, 1991 Feb DISC

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

AN COBALT LABS INC EQ 0.083% BASE;0.017% N77063 001 Dec 31, 2007 Apr CAHN

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

| | | | |
|---------|------------------|--------------|----------------------------------|
| AB | BARR | EQ 70MG BASE | N76184 001 Feb 06, 2008 Jan NEWA |
| AB | TEVA PHARMS | EQ 5MG BASE | N75710 001 Feb 06, 2008 Jan NEWA |
| AB | | EQ 10MG BASE | N75710 002 Feb 06, 2008 Jan NEWA |
| AB | | EQ 35MG BASE | N75710 003 Feb 06, 2008 Jan NEWA |
| AB | | EQ 40MG BASE | N75710 004 Feb 06, 2008 Jan NEWA |
| AB | | EQ 70MG BASE | N75710 005 Feb 06, 2008 Jan NEWA |
| FOSAMAX | | | |
| AB | MERCK AND CO INC | EQ 5MG BASE | N20560 003 Apr 25, 1997 Jan CFTG |
| AB | | EQ 10MG BASE | N20560 001 Sep 29, 1995 Jan CFTG |
| AB | | EQ 35MG BASE | N20560 004 Oct 20, 2000 Jan CFTG |
| AB | | EQ 40MG BASE | N20560 002 Sep 29, 1995 Jan CFTG |
| AB | + | EQ 70MG BASE | N20560 005 Oct 20, 2000 Jan CFTG |

ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

TEKTURN A HCT

| | | |
|----------|----------------------|----------------------------------|
| NOVARTIS | EQ 150MG BASE;12.5MG | N22107 001 Jan 18, 2008 Jan NEWA |
| | EQ 150MG BASE;25MG | N22107 002 Jan 18, 2008 Jan NEWA |
| | EQ 300MG BASE;12.5MG | N22107 003 Jan 18, 2008 Jan NEWA |
| + | EQ 300MG BASE;25MG | N22107 004 Jan 18, 2008 Jan NEWA |

ALMOTRIPTAN MALATE

TABLET; ORAL

AXERT

| | | | |
|-----|--------------------|----------------|----------------------------------|
| >A> | ORTHO MCNEIL | EQ 6.25MG BASE | N21001 001 May 07, 2001 Jun CAHN |
| >A> | + | EQ 12.5MG BASE | N21001 002 May 07, 2001 Jun CAHN |
| >D> | ORTHO MCNEIL PHARM | EQ 6.25MG BASE | N21001 001 May 07, 2001 Jun CAHN |
| >D> | + | EQ 12.5MG BASE | N21001 002 May 07, 2001 Jun CAHN |

ALOSETRON HYDROCHLORIDE

TABLET; ORAL

LOTRONEX

| | | |
|-----------------|---------------|----------------------------------|
| PROMETHEUS LABS | EQ 0.5MG BASE | N21107 002 Dec 23, 2003 Mar CAHN |
| + | EQ 1MG BASE | N21107 001 Feb 09, 2000 Mar CAHN |

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

| | | |
|--------|--------|----------------------------------|
| @ TEVA | 0.25MG | N74085 001 Feb 16, 1994 Feb DISC |
| @ | 0.5MG | N74085 002 Feb 16, 1994 Feb DISC |
| @ | 1MG | N74085 003 Feb 16, 1994 Feb DISC |
| @ | 2MG | N74085 004 Feb 26, 1996 Feb DISC |

TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

| | | | |
|----|------------|-------|----------------------------------|
| AB | INTERPHARM | 0.5MG | N78387 001 May 30, 2008 May NEWA |
| AB | | 1MG | N78387 002 May 30, 2008 May NEWA |
| AB | | 2MG | N78387 003 May 30, 2008 May NEWA |

TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

AB INTERPHARM 3MG N78387 004 May 30, 2008 May NEWA

ALVIMOPAN

CAPSULE; ORAL

ENTEREG

+ ADOLOR 12MG N21775 001 May 20, 2008 May NEWA

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HYDROCHLORIDE

AB BANNER PHARMACAPS 100MG N78720 001 May 29, 2008 May NEWA

SYRUP; ORAL

AMANTADINE HYDROCHLORIDE

@ TEVA PHARMS 50MG/5ML N73115 001 Aug 23, 1991 Feb DISC

AMIFOSTINE

INJECTABLE; INJECTION

AMIFOSTINE

AP SUN PHARM IND 500MG/VIAL N77126 001 Mar 14, 2008 Mar NEWA

ETHYOL

@ MEDIMMUNE 375MG/VIAL N20221 002 Sep 10, 1999 May CAHN

AP + 500MG/VIAL N20221 001 Dec 08, 1995 May CAHN

AP + MEDIMMUNE ONCOLOGY 500MG/VIAL N20221 001 Dec 08, 1995 Mar CFTG

>D> AMINOGLUTETHIMIDE

>D> TABLET; ORAL

>D> CYTADREN

>D> + NOVARTIS 250MG N18202 001 Jun DISC

>A> @ 250MG N18202 001 Jun DISC

AMINOPHYLLINE

SOLUTION; ORAL

AMINOPHYLLINE

>D> AA + ROXANE 105MG/5ML N88126 001 Aug 19, 1983 Jun DISC

>A> @ 105MG/5ML N88126 001 Aug 19, 1983 Jun DISC

AMINOPHYLLINE DYE FREE

>D> AA + ACTAVIS MID ATLANTIC 105MG/5ML N87727 001 Apr 16, 1982 Jun CTEC

>A> + 105MG/5ML N87727 001 Apr 16, 1982 Jun CTEC

TABLET, EXTENDED RELEASE; ORAL

PHYLLOCONTIN

@ PHARM RES ASSOC 225MG N86760 001 May CAHN

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

@ BEN VENUE 50MG/ML N76088 001 Oct 15, 2002 Apr DISC

AP HIKMA FARMACEUTICA 50MG/ML N77234 001 Feb 25, 2008 Feb NEWA

TABLET; ORAL

AMIODARONE HYDROCHLORIDE

@ TEVA 200MG N74895 001 Apr 16, 1999 Feb DISC

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HYDROCHLORIDE

| | | | | | | | | | |
|-----|----|--------|-------|--------|-----|---------|------|-----|------|
| >A> | AB | CARACO | 10MG | N40815 | 001 | Jun 27, | 2008 | Jun | NEWA |
| >A> | AB | | 25MG | N40816 | 001 | Jun 27, | 2008 | Jun | NEWA |
| >A> | AB | | 50MG | N40817 | 001 | Jun 27, | 2008 | Jun | NEWA |
| >A> | AB | | 75MG | N40818 | 001 | Jun 27, | 2008 | Jun | NEWA |
| >A> | AB | | 100MG | N40819 | 001 | Jun 27, | 2008 | Jun | NEWA |
| >A> | AB | | 150MG | N40820 | 001 | Jun 27, | 2008 | Jun | NEWA |

AMLODIPINE BESYLATE

TABLET; ORAL

AMLODIPINE BESYLATE

| | | | | | | | | |
|------------|-----------------|---------------|--------|-----|---------|------|-----|------|
| @ GENPHARM | | EQ 2.5MG BASE | N77362 | 001 | Jul 09, | 2007 | Feb | DISC |
| @ | | EQ 5MG BASE | N77362 | 002 | Jul 09, | 2007 | Feb | DISC |
| @ | | EQ 10MG BASE | N77362 | 003 | Jul 09, | 2007 | Feb | DISC |
| AB | INTERPHARM | EQ 2.5MG BASE | N78477 | 001 | Jan 16, | 2008 | Jan | NEWA |
| AB | | EQ 5MG BASE | N78477 | 002 | Jan 16, | 2008 | Jan | NEWA |
| AB | | EQ 10MG BASE | N78477 | 003 | Jan 16, | 2008 | Jan | NEWA |
| AB | MATRIX LABS LTD | EQ 2.5MG BASE | N78224 | 001 | Feb 27, | 2008 | Feb | NEWA |
| AB | | EQ 5MG BASE | N78224 | 002 | Feb 27, | 2008 | Feb | NEWA |
| AB | | EQ 10MG BASE | N78224 | 003 | Feb 27, | 2008 | Feb | NEWA |
| AB | MUTUAL PHARMA | EQ 2.5MG BASE | N78081 | 001 | Jan 31, | 2008 | Jan | NEWA |
| AB | | EQ 5MG BASE | N78081 | 002 | Jan 31, | 2008 | Jan | NEWA |
| AB | | EQ 10MG BASE | N78081 | 003 | Jan 31, | 2008 | Jan | NEWA |

AMOXICILLIN

TABLET, EXTENDED RELEASE; ORAL

MOXATAG

+ MIDDLEBROOK PHARMS 775MG

N50813 001 Jan 23, 2008 Jan NEWA

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

ANAGRELIDE HYDROCHLORIDE

| | | | | | | | | | |
|-----|----|--------|---------------|--------|-----|---------|------|-----|------|
| >D> | AB | ROXANE | EQ 0.5MG BASE | N76489 | 001 | Apr 18, | 2005 | Jun | DISC |
| >A> | | @ | EQ 0.5MG BASE | N76489 | 001 | Apr 18, | 2005 | Jun | DISC |
| >D> | AB | | EQ 1MG BASE | N76489 | 002 | Apr 18, | 2005 | Jun | DISC |
| >A> | | @ | EQ 1MG BASE | N76489 | 002 | Apr 18, | 2005 | Jun | DISC |

APROTININ

INJECTABLE; INJECTION

TRASYLOL

| | | | | | | | | |
|-----|------------------|--------------|--------|-----|---------|------|-----|------|
| >A> | + BAYER HLTHCARE | 10,000KIU/ML | N20304 | 001 | Dec 29, | 1993 | Jun | CAHN |
|-----|------------------|--------------|--------|-----|---------|------|-----|------|

APROTININ BOVINE

INJECTABLE; INJECTION

TRASYLOL

| | | | | | | | | |
|-----|----------------|--------------|--------|-----|---------|------|-----|------|
| >D> | + BAYER PHARMS | 10,000KIU/ML | N20304 | 001 | Dec 29, | 1993 | Jun | CAHN |
|-----|----------------|--------------|--------|-----|---------|------|-----|------|

ARIPIPRAZOLE

TABLET, ORALLY DISINTEGRATING; ORAL

ABILIFY

@ OTSUKA

@

20MG

30MG

N21729 004 Jun 07, 2006 Apr DISC

N21729 005 Jun 07, 2006 Apr DISC

ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL
SYNALGOS-DC

| | | | |
|-----|------------------|-------------------|----------------------------------|
| >A> | + CARACO | 356.4MG;30MG;16MG | N11483 004 Sep 06, 1983 Jun CAHN |
| >D> | + LEITNER PHARMS | 356.4MG;30MG;16MG | N11483 004 Sep 06, 1983 Jun CAHN |

ASPIRIN; CARISOPRODOL

TABLET; ORAL
SOMA COMPOUND

| | | | |
|----|---------------|-------------|----------------------------------|
| AB | + MEDA PHARMS | 325MG;200MG | N12365 005 Jul 11, 1983 May CAHN |
|----|---------------|-------------|----------------------------------|

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL
SOMA COMPOUND W/ CODEINE

| | | | |
|----|---------------|------------------|----------------------------------|
| AB | + MEDA PHARMS | 325MG;200MG;16MG | N12366 002 Jul 11, 1983 May CAHN |
|----|---------------|------------------|----------------------------------|

ASPIRIN; MEPROBAMATE

TABLET; ORAL
EQUAGESIC

| | | | |
|-----|------------------|-------------|----------------------------------|
| >A> | + CARACO | 325MG;200MG | N11702 003 Dec 29, 1983 Jun CAHN |
| >D> | + LEITNER PHARMS | 325MG;200MG | N11702 003 Dec 29, 1983 Jun CAHN |

ATENOLOL

INJECTABLE; INJECTION
TENORMIN

| | | |
|---------------|----------|----------------------------------|
| @ ASTRAZENECA | 0.5MG/ML | N19058 001 Sep 13, 1989 Feb DISC |
|---------------|----------|----------------------------------|

TABLET; ORAL
ATENOLOL

| | | |
|----------|-------|----------------------------------|
| @ PLIVA | 25MG | N74101 001 Jul 17, 1997 Feb DISC |
| @ | 50MG | N74101 002 Jul 17, 1997 Feb DISC |
| @ | 100MG | N74101 003 Jul 17, 1997 Feb DISC |
| @ SANDOZ | 25MG | N74265 001 Feb 28, 1994 Feb DISC |
| @ | 50MG | N74265 002 Feb 28, 1994 Feb DISC |
| @ | 100MG | N74265 003 Feb 28, 1994 Feb DISC |
| @ SCS | 50MG | N73676 001 Oct 30, 1992 Feb DISC |
| @ | 100MG | N73676 002 Oct 30, 1992 Feb DISC |

>D> ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

>D> TABLET; ORAL
MOTOFEN

| | | | |
|-----|-----------|-------------|---------------------|
| >D> | + VALEANT | 0.025MG;1MG | N17744 002 Jun DISC |
| >A> | @ | 0.025MG;1MG | N17744 002 Jun DISC |

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HYDROCHLORIDE W/ ATROPINE SULFATE

| | | |
|------------|---------------|---------------------|
| @ PVT FORM | 0.025MG;2.5MG | N85766 001 Apr CAHN |
|------------|---------------|---------------------|

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
ENLON-PLUS

| | | |
|------------------------|-------------------|----------------------------------|
| @ BAXTER HLTHCARE CORP | 0.14MG/ML;10MG/ML | N19677 001 Nov 06, 1991 Feb DISC |
| @ | 0.14MG/ML;10MG/ML | N19678 001 Nov 06, 1991 Feb DISC |

AZACITIDINE

INJECTABLE; IV-SC

VIDAZA

| | | | | | | | |
|-----|---|--------------|------------|------------|--------------|-----|------|
| >D> | + | PHARMION | 100MG/VIAL | N50794 001 | May 19, 2004 | Jun | CAHN |
| >A> | + | PHARMION LLC | 100MG/VIAL | N50794 001 | May 19, 2004 | Jun | CAHN |

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIVAR

| | | | | | | | |
|-----|---|---------------------|-------|------------|--------------|-----|------|
| >A> | + | MEDA PHARMS | 0.05% | N21127 001 | May 22, 2000 | Jun | CAHN |
| >D> | + | MEDPOINTE PHARM HLC | 0.05% | N21127 001 | May 22, 2000 | Jun | CAHN |

SPRAY, METERED; NASAL

ASTELIN

| | | | | | | | |
|-----|---|---------------------|-----------------------|------------|--------------|-----|------|
| >A> | + | MEDA PHARMS | EQ 0.125MG BASE/SPRAY | N20114 001 | Nov 01, 1996 | Jun | CAHN |
| >D> | + | MEDPOINTE PHARM HLC | EQ 0.125MG BASE/SPRAY | N20114 001 | Nov 01, 1996 | Jun | CAHN |

AZITHROMYCIN

FOR SUSPENSION; ORAL

AZITHROMYCIN

| | | | | | | | |
|-----|----|-------------|-------------------|------------|--------------|-----|------|
| >A> | AB | TEVA PHARMS | EQ 100MG BASE/5ML | N65419 001 | Jun 24, 2008 | Jun | NEWA |
| >A> | AB | | EQ 200MG BASE/5ML | N65419 002 | Jun 24, 2008 | Jun | NEWA |

TABLET; ORAL

AZITHROMYCIN

| | | | | | | |
|----|-----------|---------------|------------|--------------|-----|------|
| AB | WOCKHARDT | EQ 250MG BASE | N65404 001 | Feb 11, 2008 | Jan | NEWA |
| AB | | EQ 500MG BASE | N65405 001 | Feb 11, 2008 | Jan | NEWA |
| AB | | EQ 600MG BASE | N65302 003 | Feb 11, 2008 | Jan | NEWA |

AZTREONAM

INJECTABLE; INJECTION

AZACTAM

@ BRISTOL MYERS SQUIBB 500MG/VIAL

N50580 001 Dec 31, 1986 Jan DISC

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40

| | | | | | | | |
|-----|---|--------------|------------|------------|--------------|-----|------|
| >D> | + | IVAX RES LLC | 0.04MG/INH | N20911 002 | Sep 15, 2000 | Jun | CAHN |
| >A> | + | TEVA GLOBAL | 0.04MG/INH | N20911 002 | Sep 15, 2000 | Jun | CAHN |
| | | QVAR 80 | | | | | |
| >D> | + | IVAX RES LLC | 0.08MG/INH | N20911 001 | Sep 15, 2000 | Jun | CAHN |
| >A> | + | TEVA GLOBAL | 0.08MG/INH | N20911 001 | Sep 15, 2000 | Jun | CAHN |

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

| | | | | | | | |
|-----|------------------|----------|------------|--------------|--------------|------|------|
| AB | AUROBINDO PHARMA | 10MG | N78212 001 | May 22, 2008 | May | NEWA | |
| AB | | 20MG | N78212 002 | May 22, 2008 | May | NEWA | |
| AB | | 40MG | N78212 003 | May 22, 2008 | May | NEWA | |
| >D> | AB | GENPHARM | 5MG | N76476 001 | Feb 11, 2004 | Jun | DISC |
| >A> | @ | | 5MG | N76476 001 | Feb 11, 2004 | Jun | DISC |
| >D> | AB | | 10MG | N76476 002 | Feb 11, 2004 | Jun | DISC |
| >A> | @ | | 10MG | N76476 002 | Feb 11, 2004 | Jun | DISC |
| >D> | AB | | 20MG | N76476 003 | Feb 11, 2004 | Jun | DISC |
| >A> | @ | | 20MG | N76476 003 | Feb 11, 2004 | Jun | DISC |
| >D> | AB | | 40MG | N76476 004 | Feb 11, 2004 | Jun | DISC |
| >A> | @ | | 40MG | N76476 004 | Feb 11, 2004 | Jun | DISC |

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

| | | | | | | |
|----|------------------|------|------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA | 5MG | N78848 001 | May 23, 2008 | May | NEWA |
| AB | | 10MG | N78848 002 | May 23, 2008 | May | NEWA |
| AB | | 20MG | N78848 003 | May 23, 2008 | May | NEWA |
| AB | | 40MG | N78848 004 | May 23, 2008 | May | NEWA |

BENDAMUSTINE HYDROCHLORIDE

POWDER; IV (INFUSION)

TREANDA

+ CEPHALON 100MG/VIAL

N22249 001 Mar 20, 2008 Mar NEWA

BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL

NADOLOL AND BENDROFLUMETHAZIDE

| | | | | | | |
|----|-------|----------|------------|--------------|-----|------|
| AB | MYLAN | 5MG;40MG | N78688 001 | Feb 15, 2008 | Feb | NEWA |
| AB | | 5MG;80MG | N78688 002 | Feb 15, 2008 | Feb | NEWA |

BENZONATATE

CAPSULE; ORAL

BENZONATATE

| | | | | | | |
|----|---------------------|-------|------------|--------------|-----|------|
| AA | BANNER PHARMACAPS | 200MG | N81297 002 | Oct 30, 2007 | May | NEWA |
| AA | ORIT LABS LLC | 100MG | N40682 001 | Jul 30, 2007 | Jan | CAHN |
| AA | | 200MG | N40682 002 | Jul 30, 2007 | Jan | CAHN |
| AA | SUN PHARM IND S INC | 100MG | N40587 001 | Mar 19, 2008 | Mar | NEWA |
| AA | | 200MG | N40587 002 | Mar 19, 2008 | Mar | NEWA |

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

@ PVT FORM 50MG

N83206 001 Apr CAHN

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

| | | | | | | |
|----|----------------|-------|------------|--------------|-----|------|
| AA | ACTAVIS TOTOWA | 0.5MG | N40699 001 | Feb 14, 2008 | Jan | NEWA |
| AA | | 1MG | N40705 001 | Feb 14, 2008 | Jan | NEWA |
| AA | | 2MG | N40706 001 | Feb 14, 2008 | Jan | NEWA |
| | @ MUTUAL PHARM | 1MG | N81264 001 | Jan 23, 1992 | Feb | DISC |
| | @ | 2MG | N81265 001 | Jan 23, 1992 | Feb | DISC |

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE

SUSPENSION; TOPICAL

TACLONEX SCALP

+ LEO PHARM PRODS 0.064%;0.005%

N22185 001 May 09, 2008 May NEWA

BETAXOLOL HYDROCHLORIDE

TABLET; ORAL

BETAXOLOL HYDROCHLORIDE

| | | | | | | | |
|-----|----|----------|------|------------|--------------|-----|------|
| >A> | AB | KVK TECH | 10MG | N78962 001 | Jun 27, 2008 | Jun | NEWA |
| | AB | | 20MG | N78962 002 | Jun 27, 2008 | Jun | NEWA |

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

| | | | | | | |
|----|---------|-----|------------|--------------|-----|------|
| AA | LANNETT | 5MG | N40703 001 | Mar 27, 2008 | Mar | NEWA |
|----|---------|-----|------------|--------------|-----|------|

TABLET; ORAL

BETHANECHOL CHLORIDE

| | | | |
|----|---------|------|----------------------------------|
| AA | LANNETT | 10MG | N40704 001 Mar 27, 2008 Mar NEWA |
| AA | | 25MG | N40678 003 Mar 27, 2008 Mar NEWA |
| AA | | 50MG | N40677 001 Mar 27, 2008 Mar NEWA |

BISACODYL; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL

HALFLYTLYTE

| | | |
|-------------|---|----------------------------------|
| @ BRAINTREE | 5MG,N/A;N/A,210GM;N/A,0.74GM;N/A, 2.86GM;N/A,5.6GM | N21551 001 May 10, 2004 May DISC |
|-------------|---|----------------------------------|

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN SULFATE

| | | | |
|----|-----------------|-----------------------|----------------------------------|
| AP | ABRAXIS PHARM | EQ 15 UNITS BASE/VIAL | N65185 001 Jan 28, 2008 Jan NEWA |
| AP | | EQ 30 UNITS BASE/VIAL | N65185 002 Jan 28, 2008 Jan NEWA |
| AP | BEDFORD | EQ 15 UNITS BASE/VIAL | N65042 002 Oct 17, 2001 Jan CTNA |
| AP | | EQ 30 UNITS BASE/VIAL | N65042 001 Oct 17, 2001 Jan CTNA |
| AP | HOSPIRA | EQ 15 UNITS BASE/VIAL | N65031 001 Mar 10, 2000 Jan CTNA |
| AP | | EQ 30 UNITS BASE/VIAL | N65031 002 Mar 10, 2000 Jan CTNA |
| AP | PHARMACHEMIE BV | EQ 15 UNITS BASE/VIAL | N65201 001 Dec 13, 2007 Jan CTNA |
| AP | TEVA PARENTERAL | EQ 15 UNITS BASE/VIAL | N65033 001 Jun 27, 2000 Jan CTNA |
| AP | | EQ 30 UNITS BASE/VIAL | N65033 002 Jun 27, 2000 Jan CTNA |

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

BRIMONIDINE TARTRATE

| | | | |
|----|--------|------|----------------------------------|
| AT | SANDOZ | 0.2% | N78075 001 Jan 30, 2008 Jan NEWA |
|----|--------|------|----------------------------------|

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE

SYRUP; ORAL

BROMODIPHENHYDRAMINE HYDROCHLORIDE AND CODEINE PHOSPHATE

| | | |
|----------------|---------------------|----------------------------------|
| @ MORTON GROVE | 12.5MG/5ML;10MG/5ML | N88626 001 Oct 12, 1984 Feb DISC |
|----------------|---------------------|----------------------------------|

BUMETANIDE

INJECTABLE; INJECTION

BUMETANIDE

| | | | |
|----|-----------------|-----------|----------------------------------|
| AP | BAXTER HLTHCARE | 0.25MG/ML | N79196 001 Apr 30, 2008 Apr NEWA |
|----|-----------------|-----------|----------------------------------|

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

| | | |
|-----------|------------------|----------------------------------|
| @ HOSPIRA | 0.5%;0.005MG/ML | N71169 001 Jun 16, 1988 Apr DISC |
| @ | 0.75%;0.005MG/ML | N71171 001 Jun 16, 1988 Apr DISC |

BUPIVACAINE HYDROCHLORIDE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

DUOCAIN

| | | |
|-------------|---|----------------------------------|
| @ AMPHASTAR | EQ 0.375% (37.5MG/10ML);EQ 1% (100MG/10ML) | N21496 001 May 23, 2003 May DISC |
|-------------|---|----------------------------------|

BUPROPION HYDROBROMIDE

TABLET, EXTENDED RELEASE; ORAL

APLENZIN

| | | |
|---------------------|-------|----------------------------------|
| + BIOVAIL LABS INTL | 174MG | N22108 001 Apr 23, 2008 Apr NEWA |
|---------------------|-------|----------------------------------|

TABLET, EXTENDED RELEASE; ORAL

APLENZIN

| | |
|-------------------|-------|
| BIOVAIL LABS INTL | 348MG |
| | 522MG |

| | | | |
|------------|--------------|-----|------|
| N22108 002 | Apr 23, 2008 | Apr | NEWA |
| N22108 003 | Apr 23, 2008 | Apr | NEWA |

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

| | | |
|-----|---------|-------|
| AB1 | ACTAVIS | 150MG |
| AB2 | | 150MG |
| AB1 | | 150MG |

| | | | |
|------------|--------------|-----|------|
| N77455 002 | Mar 12, 2008 | Mar | NEWA |
| N77475 001 | Mar 12, 2008 | Mar | CTEC |
| N77475 001 | Mar 12, 2008 | Feb | NEWA |

BUSULFAN

INJECTABLE; INJECTION

BUSULFEX

| | | | |
|-----|---|-------------------|--------|
| >A> | + | OTSUKA PHARM | 6MG/ML |
| >D> | + | PDL BIOPHARMA INC | 6MG/ML |

| | | | |
|------------|--------------|-----|------|
| N20954 001 | Feb 04, 1999 | Jun | CAHN |
| N20954 001 | Feb 04, 1999 | Jun | CAHN |

BUTABARBITAL SODIUM

ELIXIR; ORAL

BUTISOL SODIUM

| | | | |
|-----|---|---------------------|----------|
| >A> | + | MEDA PHARMS | 30MG/5ML |
| >D> | + | MEDPOINTE PHARM HLC | 30MG/5ML |

| | | |
|------------|-----|------|
| N85380 001 | Jun | CAHN |
| N85380 001 | Jun | CAHN |

TABLET; ORAL

BUTISOL SODIUM

| | | | |
|-----|----|-----------------------|-------|
| >A> | | @ MEDA PHARMS | 15MG |
| >A> | AA | + | 30MG |
| >A> | | + | 50MG |
| >A> | | @ | 100MG |
| >D> | | @ MEDPOINTE PHARM HLC | 15MG |
| >D> | AA | + | 30MG |
| >D> | | + | 50MG |
| >D> | | @ | 100MG |

| | | |
|------------|-----|------|
| N00793 002 | Jun | CAHN |
| N00793 004 | Jun | CAHN |
| N00793 003 | Jun | CAHN |
| N00793 005 | Jun | CAHN |
| N00793 002 | Jun | CAHN |
| N00793 004 | Jun | CAHN |
| N00793 003 | Jun | CAHN |
| N00793 005 | Jun | CAHN |

CABERGOLINE

TABLET; ORAL

CABERGOLINE

| | | | |
|----|-----------------|------------------------|-------|
| AB | COBALT LABS INC | 0.5MG | |
| AB | + | PAR PHARM | 0.5MG |
| | | DOSTINEX | |
| | | @ PHARMACIA AND UPJOHN | 0.5MG |

| | | | |
|------------|--------------|-----|------|
| N78035 001 | Apr 21, 2008 | Apr | NEWA |
| N76310 001 | Dec 29, 2005 | Apr | CRLD |
| N20664 001 | Dec 23, 1996 | Apr | DISC |

CAFFEINE CITRATE

SOLUTION; ORAL

CAFFEINE CITRATE

| | | |
|----|---------------------|---------------------------------------|
| AA | ABRAXIS PHARM PRODS | EQ 30MG BASE/3ML (EQ 10MG BASE/ML) |
|----|---------------------|---------------------------------------|

| | | | |
|------------|--------------|-----|------|
| N78002 001 | Jan 31, 2008 | Jan | NEWA |
|------------|--------------|-----|------|

CALCIPOTRIENE

SOLUTION; TOPICAL

CALCIPOTRIENE

| | | | |
|----|------------|-----------|--------|
| AT | NYCOMED US | 0.005% | |
| | DOVONEX | | |
| AT | + | LEO PHARM | 0.005% |

| | | | |
|------------|--------------|-----|------|
| N78305 001 | May 06, 2008 | Apr | NEWA |
| N20611 001 | Mar 03, 1997 | Apr | CFTG |

CALCITRIOL

INJECTABLE; INJECTION

CALCITRIOL

| | | | |
|----|-------|------------|----------------------------------|
| AP | AKORN | 0.001MG/ML | N78066 001 Jan 29, 2008 Jan NEWA |
| AP | | 0.002MG/ML | N78066 002 Jan 29, 2008 Jan NEWA |

CALCIUM ACETATE

CAPSULE; ORAL

CALCIUM ACETATE

| | | | |
|----|-------------------|------------------|----------------------------------|
| AB | ROXANE | EQ 169MG CALCIUM | N77728 001 Feb 26, 2008 Feb NEWA |
| AB | + FRESENIUS MEDCL | EQ 169MG CALCIUM | N21160 003 Apr 02, 2001 Feb CFTG |
| | TABLET; ORAL | | |
| | CALCIUM ACETATE | | |
| | @ ROXANE | EQ 169MG CALCIUM | N77693 001 Jan 30, 2008 Apr DISC |
| | + | EQ 169MG CALCIUM | N77693 001 Jan 30, 2008 Jan NEWA |

CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ATACAND HCT

ASTRAZENECA

32MG;12.5MG

N21093 002 Sep 05, 2000 May CRLD

+ 32MG;25MG

N21093 003 May 16, 2008 May NEWA

CAPTOPRIL

TABLET; ORAL

Captopril

@ SANDOZ 12.5MG

N74481 001 Feb 13, 1996 Feb DISC

@ 12.5MG

N74519 001 Feb 13, 1996 Feb DISC

@ 25MG

N74481 002 Feb 13, 1996 Feb DISC

@ 25MG

N74519 002 Feb 13, 1996 Feb DISC

@ 50MG

N74481 003 Feb 13, 1996 Feb DISC

@ 50MG

N74519 003 Feb 13, 1996 Feb DISC

@ 100MG

N74481 004 Feb 13, 1996 Feb DISC

@ 100MG

N74519 004 Feb 13, 1996 Feb DISC

@ WATSON LABS 12.5MG

N74576 001 Apr 23, 1996 Feb DISC

@ 25MG

N74576 002 Apr 23, 1996 Feb DISC

@ 50MG

N74576 003 Apr 23, 1996 Feb DISC

@ 100MG

N74576 004 Apr 23, 1996 Feb DISC

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

| | | | |
|----|------------|------------|----------------------------------|
| AB | APOTEX INC | 10MG;100MG | N77120 001 Jun 02, 2008 May NEWA |
| AB | | 25MG;100MG | N77120 002 Jun 02, 2008 May NEWA |
| AB | | 25MG;250MG | N77120 003 Jun 02, 2008 May NEWA |

TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA

| | | | |
|-----|-------------|------------|----------------------------------|
| >D> | AB KV PHARM | 50MG;200MG | N76663 001 Jun 24, 2004 Jun CTEC |
| >A> | BX | 50MG;200MG | N76663 001 Jun 24, 2004 Jun CTEC |

CARBINOXAMINE MALEATE

SOLUTION; ORAL

CARBINOXAMINE MALEATE

| | | | |
|----|-------------|---------|----------------------------------|
| AA | BOCA PHARMA | 4MG/5ML | N40814 001 Feb 26, 2008 Feb NEWA |
| AA | + MIKART | 4MG/5ML | N40458 001 Apr 25, 2003 Feb CTEC |

TABLET; ORAL

CARBINOXAMINE MALEATE

| | | | |
|----|-------------|-----|----------------------------------|
| AA | BOCA PHARMA | 4MG | N40639 002 May 30, 2008 May NEWA |
| AA | + MIKART | 4MG | N40442 001 Mar 19, 2003 May CTEC |

CARBOPLATIN

INJECTABLE; IV (INFUSION)

CARBOPLATIN

| | | | |
|----|--------------|------------------------|----------------------------------|
| AP | EBEWE PHARMA | EQ 50MG/5ML(10MG/ML) | N78280 001 May 08, 2008 Apr NEWA |
| AP | | EQ 150MG/15ML(10MG/ML) | N78280 002 May 08, 2008 Apr NEWA |
| AP | | EQ 450MG/45ML(10MG/ML) | N78280 003 May 08, 2008 Apr NEWA |

CARISOPRODOL

CAPSULE; ORAL

SOMA

@ MEDA PHARMS

250MG

N11792 003

May CAHN

TABLET; ORAL

SOMA

MEDA PHARMS

250MG

N11792 004 Sep 13, 2007 May CAHN

| | | | |
|----|---|-------|---------------------|
| AA | + | 350MG | N11792 001 May CAHN |
|----|---|-------|---------------------|

CARMUSTINE

IMPLANT; INTRACRANIAL

GLIADEL

| | | | | |
|-----|---|-----------------|-------|----------------------------------|
| >A> | + | EISAI MEDCL RES | 7.7MG | N20637 001 Sep 23, 1996 Jun CAHN |
| >D> | + | MGI PHARMA INC | 7.7MG | N20637 001 Sep 23, 1996 Jun CAHN |

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

| | | | |
|----|-------|---------------|----------------------------------|
| AB | HIKMA | EQ 500MG BASE | N65311 001 Feb 07, 2006 Jan CAHN |
|----|-------|---------------|----------------------------------|

FOR SUSPENSION; ORAL

CEFADROXIL

| | | | |
|----|-------|-------------------|----------------------------------|
| AB | LUPIN | EQ 250MG BASE/5ML | N65396 001 Feb 21, 2008 Feb NEWA |
| AB | | EQ 500MG BASE/5ML | N65396 002 Feb 21, 2008 Feb NEWA |

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

KEFZOL

| | | | |
|----|------------|--------------------|---------------------|
| AP | ACS DOBFAR | EQ 500MG BASE/VIAL | N61773 002 Mar CMFD |
| AP | | EQ 1GM BASE/VIAL | N61773 003 Mar CMFD |
| AP | | EQ 10GM BASE/VIAL | N61773 004 Mar CMFD |

CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION

CEFEPIME HYDROCHLORIDE

| | | | |
|----|------------|------------------|----------------------------------|
| AP | ACS DOBFAR | EQ 1GM BASE/VIAL | N65441 001 Mar 20, 2008 Mar NEWA |
| AP | | EQ 2GM BASE/VIAL | N65441 002 Mar 20, 2008 Mar NEWA |

CEFIXIME

TABLET; ORAL

SUPRAX

| | | | |
|---|-------|-------|----------------------------------|
| + | LUPIN | 400MG | N65130 001 Feb 12, 2004 Apr CMFD |
|---|-------|-------|----------------------------------|

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

| | | | | | | | | |
|-----|------------------------------|-------------------|--|--------|-----|--------------|-----|------|
| >D> | CEFOBID | | | | | | | |
| >D> | + PFIZER | EQ 1GM BASE/VIAL | | N50551 | 001 | Nov 18, 1982 | Jun | DISC |
| >A> | @ | EQ 1GM BASE/VIAL | | N50551 | 001 | Nov 18, 1982 | Jun | DISC |
| >D> | + | EQ 2GM BASE/VIAL | | N50551 | 002 | Nov 18, 1982 | Jun | DISC |
| >A> | @ | EQ 2GM BASE/VIAL | | N50551 | 002 | Nov 18, 1982 | Jun | DISC |
| >D> | + | EQ 10GM BASE/VIAL | | N50551 | 003 | Mar 05, 1990 | Jun | DISC |
| >A> | @ | EQ 10GM BASE/VIAL | | N50551 | 003 | Mar 05, 1990 | Jun | DISC |
| >D> | CEFOBID IN PLASTIC CONTAINER | | | | | | | |
| >D> | + PFIZER | EQ 20MG BASE/ML | | N50613 | 002 | Jul 31, 1987 | Jun | DISC |
| >A> | @ | EQ 20MG BASE/ML | | N50613 | 002 | Jul 31, 1987 | Jun | DISC |
| >D> | + | EQ 40MG BASE/ML | | N50613 | 001 | Jul 23, 1986 | Jun | DISC |
| >A> | @ | EQ 40MG BASE/ML | | N50613 | 001 | Jul 23, 1986 | Jun | DISC |

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

| | | | | | | | | |
|-----|----|-----------|--------------------|--------|-----|--------------|-----|------|
| >A> | AP | WOCKHARDT | EQ 500MG BASE/VIAL | N65197 | 002 | Jun 20, 2008 | Jun | NEWA |
| >A> | AP | | EQ 2GM BASE/VIAL | N65197 | 003 | Jun 20, 2008 | Jun | NEWA |

CEFPODOXIME PROXETIL

TABLET; ORAL

CEFPODOXIME PROXETIL

| | | | | | | | |
|----|--------|---------------|--------|-----|--------------|-----|------|
| AB | SANDOZ | EQ 100MG BASE | N65462 | 001 | May 28, 2008 | May | NEWA |
| AB | | EQ 200MG BASE | N65462 | 002 | May 28, 2008 | May | NEWA |

CEFPROZIL

TABLET; ORAL

CEFPROZIL

| | | | | | | | |
|----|------------|-------|--------|-----|--------------|-----|------|
| AB | APOTEX INC | 250MG | N65327 | 001 | Mar 26, 2008 | Mar | NEWA |
| AB | | 500MG | N65327 | 002 | Mar 26, 2008 | Mar | NEWA |

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION

CEFIZOX

| | | | | | | | |
|-----|------------------------------|-------------------|--------|-----|--------------|-----|------|
| >D> | + ASTELLAS | EQ 1GM BASE/VIAL | N63294 | 002 | Mar 31, 1994 | Jun | DISC |
| >A> | @ | EQ 1GM BASE/VIAL | N63294 | 002 | Mar 31, 1994 | Jun | DISC |
| >D> | + | EQ 2GM BASE/VIAL | N50560 | 003 | Sep 15, 1983 | Jun | DISC |
| >A> | @ | EQ 2GM BASE/VIAL | N50560 | 003 | Sep 15, 1983 | Jun | DISC |
| >D> | | EQ 2GM BASE/VIAL | N63294 | 003 | Mar 31, 1994 | Jun | DISC |
| >A> | @ | EQ 2GM BASE/VIAL | N63294 | 003 | Mar 31, 1994 | Jun | DISC |
| >D> | | EQ 10GM BASE/VIAL | N50560 | 005 | Mar 19, 1993 | Jun | DISC |
| >A> | @ | EQ 10GM BASE/VIAL | N50560 | 005 | Mar 19, 1993 | Jun | DISC |
| >D> | CEFIZOX IN PLASTIC CONTAINER | | | | | | |
| >D> | + ASTELLAS | EQ 20MG BASE/ML | N50589 | 003 | Apr 13, 1995 | Jun | DISC |
| >A> | @ | EQ 20MG BASE/ML | N50589 | 003 | Apr 13, 1995 | Jun | DISC |
| >D> | + | EQ 40MG BASE/ML | N50589 | 004 | Apr 13, 1995 | Jun | DISC |
| >A> | @ | EQ 40MG BASE/ML | N50589 | 004 | Apr 13, 1995 | Jun | DISC |

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV

CEFTRIAXONE

| | | | | | | | |
|----|----------|--------------------|--------|-----|--------------|-----|------|
| AP | LUITPOLD | EQ 250MG BASE/VIAL | N65305 | 001 | Jan 11, 2008 | Jan | NEWA |
| AP | | EQ 500MG BASE/VIAL | N65305 | 002 | Jan 11, 2008 | Jan | NEWA |

INJECTABLE; IM-IVCEFTRIAXONE

| | | | | | | |
|----|----------|------------------|------------|--------------|-----|------|
| AP | LUITPOLD | EQ 1GM BASE/VIAL | N65305 003 | Jan 11, 2008 | Jan | NEWA |
| AP | | EQ 2GM BASE/VIAL | N65305 004 | Jan 11, 2008 | Jan | NEWA |

CEFUROXIME AXETILFOR SUSPENSION; ORALCEFTIN

| | | | | | | |
|----|-----------------|-------------------|------------|--------------|-----|------|
| AB | GLAXOSMITHKLINE | EQ 125MG BASE/5ML | N50672 001 | Jun 30, 1994 | Jan | CFTG |
|----|-----------------|-------------------|------------|--------------|-----|------|

| | | | | | | |
|----|---|-------------------|------------|--------------|-----|------|
| AB | + | EQ 250MG BASE/5ML | N50672 002 | Apr 29, 1997 | Jan | CFTG |
|----|---|-------------------|------------|--------------|-----|------|

CEFUROXIME AXETIL

| | | | | | | |
|----|---------|-------------------|------------|--------------|-----|------|
| AB | RANBAXY | EQ 125MG BASE/5ML | N65323 001 | Feb 05, 2008 | Jan | NEWA |
|----|---------|-------------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------------------|------------|--------------|-----|------|
| AB | | EQ 250MG BASE/5ML | N65323 002 | Feb 05, 2008 | Jan | NEWA |
|----|--|-------------------|------------|--------------|-----|------|

TABLET; ORALCEFUROXIME AXETIL

| | | | | | | |
|----|-----------------|---------------|------------|--------------|-----|------|
| AB | ORCHID HLTHCARE | EQ 125MG BASE | N65359 001 | Feb 15, 2008 | Jan | NEWA |
|----|-----------------|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------------|------------|--------------|-----|------|
| AB | | EQ 250MG BASE | N65359 002 | Feb 15, 2008 | Jan | NEWA |
|----|--|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------------|------------|--------------|-----|------|
| AB | | EQ 500MG BASE | N65359 003 | Feb 15, 2008 | Jan | NEWA |
|----|--|---------------|------------|--------------|-----|------|

CEPHALEXINCAPSULE; ORALKEFLEX

| | | | | | | |
|-----|------------|---------------|------------|--------------|-----|------|
| >D> | LEX PHARMS | EQ 333MG BASE | N50405 004 | May 12, 2006 | Jun | DISC |
|-----|------------|---------------|------------|--------------|-----|------|

| | | | | | | |
|-----|---|---------------|------------|--------------|-----|------|
| >A> | @ | EQ 333MG BASE | N50405 004 | May 12, 2006 | Jun | DISC |
|-----|---|---------------|------------|--------------|-----|------|

CETIRIZINE HYDROCHLORIDESYRUP; ORALCERTIRIZINE HYDROCHLORIDE

| | | | | | | |
|----|-------------|---------|------------|--------------|-----|------|
| AA | TEVA PHARMS | 5MG/5ML | N77279 001 | May 27, 2008 | May | NEWA |
|----|-------------|---------|------------|--------------|-----|------|

CETIRIZINE HYDROCHLORIDE

| | | | | | | | |
|-----|----|------------|---------|------------|--------------|-----|------|
| >A> | AA | APOTEX INC | 5MG/5ML | N78412 001 | Jun 18, 2008 | Jun | NEWA |
|-----|----|------------|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|----------------|---------|------------|--------------|-----|------|
| >A> | AA | PERRIGO ISRAEL | 5MG/5ML | N78398 001 | Jun 17, 2008 | Jun | NEWA |
|-----|----|----------------|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|---------|---------|------------|--------------|-----|------|
| >A> | AA | RANBAXY | 5MG/5ML | N77472 001 | Jun 18, 2008 | Jun | NEWA |
|-----|----|---------|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|------|---------|------------|--------------|-----|------|
| >A> | AA | TARO | 5MG/5ML | N76601 001 | Jun 20, 2008 | Jun | NEWA |
|-----|----|------|---------|------------|--------------|-----|------|

ZYRTEC

| | | | | | | | |
|----|---|-----------------|---------|------------|--------------|-----|------|
| AA | + | MCNEIL CONSUMER | 5MG/5ML | N20346 001 | Sep 27, 1996 | May | CFTG |
|----|---|-----------------|---------|------------|--------------|-----|------|

| | | | | | | | |
|----|---|--|---------|------------|--------------|-----|------|
| AA | + | | 5MG/5ML | N20346 001 | Sep 27, 1996 | Jan | CAHN |
|----|---|--|---------|------------|--------------|-----|------|

CHLORPHENIRAMINE MALEATETABLET; ORALCHLORPHENIRAMINE MALEATE

| | | | | |
|------------|-----|------------|-----|------|
| @ PVT FORM | 4MG | N80786 001 | Apr | CAHN |
|------------|-----|------------|-----|------|

CHLORPROMAZINE HYDROCHLORIDE

| | | | | | | |
|-----|-------------------|--|--|--|--|--|
| >D> | CONCENTRATE; ORAL | | | | | |
|-----|-------------------|--|--|--|--|--|

| | | | | | | |
|-----|------------------------------|--|--|--|--|--|
| >D> | CHLORPROMAZINE HYDROCHLORIDE | | | | | |
|-----|------------------------------|--|--|--|--|--|

| | | | | | | | |
|-----|----|----------------------|----------|------------|--|-----|------|
| >D> | AA | ACTAVIS MID ATLANTIC | 100MG/ML | N86863 001 | | Jun | DISC |
|-----|----|----------------------|----------|------------|--|-----|------|

| | | | | | | | |
|-----|---|--|----------|------------|--|-----|------|
| >A> | @ | | 100MG/ML | N86863 001 | | Jun | DISC |
|-----|---|--|----------|------------|--|-----|------|

| | | | | | | | |
|-----|----|-------------|---------|------------|--------------|-----|------|
| >D> | AA | PHARM ASSOC | 30MG/ML | N40231 001 | Dec 30, 1999 | Jun | DISC |
|-----|----|-------------|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|---|--|---------|------------|--------------|-----|------|
| >A> | @ | | 30MG/ML | N40231 001 | Dec 30, 1999 | Jun | DISC |
|-----|---|--|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|----------|------------|--------------|-----|------|
| >D> | AA | | 100MG/ML | N40224 001 | Jan 26, 1999 | Jun | DISC |
|-----|----|--|----------|------------|--------------|-----|------|

| | | | | | | | |
|-----|---|--|----------|------------|--------------|-----|------|
| >A> | @ | | 100MG/ML | N40224 001 | Jan 26, 1999 | Jun | DISC |
|-----|---|--|----------|------------|--------------|-----|------|

| | | | | | | | |
|-----|---------------------------------------|--|--|--|--|--|--|
| >D> | CHLORPROMAZINE HYDROCHLORIDE INTENSOL | | | | | | |
|-----|---------------------------------------|--|--|--|--|--|--|

| | | | | | | | |
|-----|----|--------|---------|------------|--------------|-----|------|
| >D> | AA | ROXANE | 30MG/ML | N88157 001 | Apr 27, 1983 | Jun | DISC |
|-----|----|--------|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|---|--|---------|------------|--------------|-----|------|
| >A> | @ | | 30MG/ML | N88157 001 | Apr 27, 1983 | Jun | DISC |
|-----|---|--|---------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|----------|------------|--------------|-----|------|
| >D> | AA | | 100MG/ML | N88158 001 | Apr 27, 1983 | Jun | DISC |
|-----|----|--|----------|------------|--------------|-----|------|

>D> CONCENTRATE; ORAL
 >D> CHLORPROMAZINE HYDROCHLORIDE INTENSOL
 >A> @ ROXANE 100MG/ML N88158 001 Apr 27, 1983 Jun DISC
 >D> SONAZINE
 >D> AA SANDOZ 30MG/ML N80983 004 Jun DISC
 >A> @ 30MG/ML N80983 004 Jun DISC
 >D> AA 100MG/ML N80983 005 Jun DISC
 >A> @ 100MG/ML N80983 005 Jun DISC
 >D> THORAZINE
 >D> AA + GLAXOSMITHKLINE 30MG/ML N09149 032 Jun DISC
 >A> @ 30MG/ML N09149 032 Jun DISC
 >D> AA + 100MG/ML N09149 043 Jun DISC
 >A> @ 100MG/ML N09149 043 Jun DISC
 INJECTABLE; INJECTION
 CHLORPROMAZINE HYDROCHLORIDE
 >D> AP BAXTER HLTHCARE 25MG/ML N83329 001 Jun CRLD
 >A> + 25MG/ML N83329 001 Jun CRLD
 >D> THORAZINE
 >D> AP + GLAXOSMITHKLINE 25MG/ML N09149 011 Jun DISC
 >A> @ 25MG/ML N09149 011 Jun DISC
 >D> SYRUP; ORAL
 >D> SONAZINE
 >D> AA SANDOZ 10MG/5ML N83040 001 Jun DISC
 >A> @ 10MG/5ML N83040 001 Jun DISC
 >D> THORAZINE
 >D> AA + GLAXOSMITHKLINE 10MG/5ML N09149 022 Jun DISC
 >A> @ 10MG/5ML N09149 022 Jun DISC
 TABLET; ORAL
 CHLORPROMAZINE HYDROCHLORIDE
 @ PVT FORM 25MG N80340 001 Apr CAHN
 @ 50MG N80340 002 Apr CAHN
 @ 200MG N80340 003 Apr CAHN

CHLORZOXAZONE

TABLET; ORAL
 PARAFON FORTE DSC
 >A> AA + ORTHO MCNEIL 500MG N11529 002 Jun 15, 1987 Jun CAHN
 >D> AA + ORTHO MCNEIL PHARM 500MG N11529 002 Jun 15, 1987 Jun CAHN
 >D> STRIFON FORTE DSC
 >D> AA FERNDALE LABS 500MG N81008 001 Dec 23, 1988 Jun DISC
 >A> @ 500MG N81008 001 Dec 23, 1988 Jun DISC

CICLESONIDE

AEROSOL, METERED; INHALATION
 ALVESCO
 NYCOMED US 0.08MG/INH N21658 002 Jan 10, 2008 Jan NEWA
 + 0.16MG/INH N21658 003 Jan 10, 2008 Jan NEWA

CICLOPIROX

GEL; TOPICAL
 CICLOPIROX
 AB NYCOMED US 0.77% N77896 001 Jun 10, 2008 May NEWA
 LOPROX
 AB + MEDICIS 0.77% N20519 001 Jul 21, 1997 May CFTG

CIPROFLOXACIN

FOR SUSPENSION; ORAL

CIPRO

| | | | | | | | |
|-----|----------------|-----------|------------|---------|------|-----|------|
| >A> | BAYER HLTHCARE | 250MG/5ML | N20780 001 | Sep 26, | 1997 | Jun | CAHN |
| >A> | + | 500MG/5ML | N20780 002 | Sep 26, | 1997 | Jun | CAHN |
| >D> | BAYER PHARMS | 250MG/5ML | N20780 001 | Sep 26, | 1997 | Jun | CAHN |
| >D> | + | 500MG/5ML | N20780 002 | Sep 26, | 1997 | Jun | CAHN |

INJECTABLE; INJECTION

CIPRO

| | | | | | | | | |
|---|---|----------------|------------------------|------------|---------|------|-----|------|
| >A> AP | + | BAYER HLTHCARE | 400MG/40ML (10MG/ML) | N19847 001 | Dec 26, | 1990 | Jun | CAHN |
| >A> AP | + | | 200MG/20ML (10MG/ML) | N19847 002 | Dec 26, | 1990 | Jun | CAHN |
| >A> | @ | | 1200MG/120ML (10MG/ML) | N19847 003 | Dec 26, | 1990 | Jun | CAHN |
| >D> AP | + | BAYER PHARMS | 400MG/40ML (10MG/ML) | N19847 001 | Dec 26, | 1990 | Jun | CAHN |
| >D> | @ | | 1200MG/120ML (10MG/ML) | N19847 003 | Dec 26, | 1990 | Jun | CAHN |
| >D> AP | + | | 200MG/20ML (10MG/ML) | N19847 002 | Dec 26, | 1990 | Jun | CAHN |
| CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | | | |
| >A> AP | + | BAYER HLTHCARE | 200MG/100ML | N19857 001 | Dec 26, | 1990 | Jun | CAHN |
| >A> AP | + | | 400MG/200ML | N19857 002 | Dec 26, | 1990 | Jun | CAHN |
| >D> AP | + | BAYER PHARMS | 200MG/100ML | N19857 001 | Dec 26, | 1990 | Jun | CAHN |
| AP | + | | 200MG/100ML | N19857 001 | Dec 26, | 1990 | Mar | CFTG |
| >D> AP | + | | 400MG/200ML | N19857 002 | Dec 26, | 1990 | Jun | CAHN |
| AP | + | | 400MG/200ML | N19857 002 | Dec 26, | 1990 | Mar | CFTG |

CIPROFLOXACIN

| | | | | | | | |
|----|---------------------|----------------------|------------|---------|------|-----|------|
| AP | CLARIS LIFESCIENCES | 200MG/20ML (10MG/ML) | N78062 001 | Apr 29, | 2008 | Apr | NEWA |
| AP | | 400MG/40ML (10MG/ML) | N78062 002 | Apr 29, | 2008 | Apr | NEWA |

CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | | | | |
|----|---------------------|-------------|------------|---------|------|-----|------|
| AP | ACS DOBFAR INFO SA | 200MG/100ML | N78252 001 | Mar 18, | 2008 | Mar | NEWA |
| AP | | 400MG/200ML | N78252 002 | Mar 18, | 2008 | Mar | NEWA |
| AP | BAXTER HLTHCARE | 200MG/100ML | N77888 001 | Mar 18, | 2008 | Mar | NEWA |
| AP | | 400MG/200ML | N77888 002 | Mar 18, | 2008 | Mar | NEWA |
| AP | BEDFORD | 200MG/100ML | N78114 001 | Mar 18, | 2008 | Mar | NEWA |
| AP | | 400MG/200ML | N78114 002 | Mar 18, | 2008 | Mar | NEWA |
| AP | CLARIS LIFESCIENCES | 200MG/100ML | N78024 001 | Mar 18, | 2008 | Mar | NEWA |
| AP | | 400MG/200ML | N78024 002 | Mar 18, | 2008 | Mar | NEWA |
| AP | HIKMA FARMACEUTICA | 200MG/100ML | N76757 001 | Apr 21, | 2008 | Apr | NEWA |
| AP | HOSPIRA | 200MG/100ML | N77753 001 | Mar 18, | 2008 | Mar | NEWA |
| AP | | 400MG/200ML | N77753 002 | Mar 18, | 2008 | Mar | NEWA |
| AP | TEVA PARENTERAL | 200MG/100ML | N77138 001 | Mar 18, | 2008 | Mar | NEWA |
| AP | | 400MG/200ML | N77138 002 | Mar 18, | 2008 | Mar | NEWA |

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN

| | | | | | | | |
|--------|---------|--------------|------------|---------|------|-----|------|
| >A> AT | FDC LTD | EQ 0.3% BASE | N77568 001 | Jun 30, | 2008 | Jun | NEWA |
|--------|---------|--------------|------------|---------|------|-----|------|

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN HYDROCHLORIDE

| | | | | | | | |
|----|-------------|--------------|------------|---------|------|-----|------|
| AT | PHARMAFORCE | EQ 0.3% BASE | N78598 001 | Jan 16, | 2008 | Jan | NEWA |
|----|-------------|--------------|------------|---------|------|-----|------|

TABLET; ORAL

CIPRO

| | | | | | | | |
|--------|----------------|---------------|------------|---------|------|-----|------|
| >A> AB | BAYER HLTHCARE | EQ 100MG BASE | N19537 001 | Apr 08, | 1996 | Jun | CAHN |
| >A> AB | | EQ 250MG BASE | N19537 002 | Oct 22, | 1987 | Jun | CAHN |
| >A> AB | | EQ 500MG BASE | N19537 003 | Oct 22, | 1987 | Jun | CAHN |
| >A> AB | + | EQ 750MG BASE | N19537 004 | Oct 22, | 1987 | Jun | CAHN |
| >D> AB | BAYER PHARMS | EQ 100MG BASE | N19537 001 | Apr 08, | 1996 | Jun | CAHN |
| >D> AB | | EQ 250MG BASE | N19537 002 | Oct 22, | 1987 | Jun | CAHN |

TABLET; ORAL

CIPRO

| | | | | | | | | | |
|------------------------------------|----|----------------|---------------|--------|-----|---------|------|-----|------|
| >D> | AB | BAYER PHARMS | EQ 500MG BASE | N19537 | 003 | Oct 22, | 1987 | Jun | CAHN |
| >D> | AB | + | EQ 750MG BASE | N19537 | 004 | Oct 22, | 1987 | Jun | CAHN |
| CIPROFLOXACIN HYDROCHLORIDE | | | | | | | | | |
| >D> | AB | MARTEC USA LLC | EQ 250MG BASE | N76138 | 001 | Jun 09, | 2004 | Jun | CTEC |
| >A> | BX | | EQ 250MG BASE | N76138 | 001 | Jun 09, | 2004 | Jun | CTEC |
| >D> | AB | | EQ 500MG BASE | N76138 | 002 | Jun 09, | 2004 | Jun | CTEC |
| >A> | BX | | EQ 500MG BASE | N76138 | 002 | Jun 09, | 2004 | Jun | CTEC |
| >D> | AB | | EQ 750MG BASE | N76138 | 003 | Jun 09, | 2004 | Jun | CTEC |
| >A> | BX | | EQ 750MG BASE | N76138 | 003 | Jun 09, | 2004 | Jun | CTEC |
| >D> | AB | PLIVA | EQ 100MG BASE | N76426 | 001 | Jun 15, | 2005 | Jun | CTEC |
| >A> | BX | | EQ 100MG BASE | N76426 | 001 | Jun 15, | 2005 | Jun | CTEC |
| >D> | AB | | EQ 250MG BASE | N76426 | 002 | Jun 15, | 2005 | Jun | CTEC |
| >A> | BX | | EQ 250MG BASE | N76426 | 002 | Jun 15, | 2005 | Jun | CTEC |
| >D> | AB | | EQ 500MG BASE | N76426 | 003 | Jun 15, | 2005 | Jun | CTEC |
| >A> | BX | | EQ 500MG BASE | N76426 | 003 | Jun 15, | 2005 | Jun | CTEC |
| >D> | AB | | EQ 750MG BASE | N76426 | 004 | Jun 15, | 2005 | Jun | CTEC |
| >A> | BX | | EQ 750MG BASE | N76426 | 004 | Jun 15, | 2005 | Jun | CTEC |

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CIPRO XR

| | | | | | | | | | | |
|-----|----|---|----------------|-------------------------|--------|-----|---------|------|-----|------|
| >A> | AB | + | BAYER HLTHCARE | 212.6MG;EQ 287.5MG BASE | N21473 | 001 | Dec 13, | 2002 | Jun | CAHN |
| >A> | AB | + | | 425.2MG;EQ 574.9MG BASE | N21473 | 002 | Aug 28, | 2003 | Jun | CAHN |
| >D> | AB | + | BAYER PHARMS | 212.6MG;EQ 287.5MG BASE | N21473 | 001 | Dec 13, | 2002 | Jun | CAHN |
| >D> | AB | + | | 425.2MG;EQ 574.9MG BASE | N21473 | 002 | Aug 28, | 2003 | Jun | CAHN |

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

| | | | | | | | | |
|----|------------------|--------------|--------|-----|---------|------|-----|------|
| AB | MATRIX LABS INC | EQ 10MG BASE | N77042 | 001 | Nov 05, | 2004 | Mar | CAHN |
| AB | | EQ 20MG BASE | N77042 | 002 | Nov 05, | 2004 | Mar | CAHN |
| AB | | EQ 40MG BASE | N77042 | 003 | Nov 05, | 2004 | Mar | CAHN |
| AB | NATCO PHARMA LTD | EQ 20MG BASE | N77141 | 002 | Apr 10, | 2008 | Mar | NEWA |
| AB | | EQ 40MG BASE | N77141 | 001 | Apr 10, | 2008 | Mar | NEWA |

CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE

SOLUTION; IRRIGATION

UROLOGIC G IN PLASTIC CONTAINER

| | | | | | | | |
|-----------|--|--------|-----|---------|------|-----|------|
| @ HOSPIRA | 3.24GM/100ML;380MG/100ML;430MG/10 0ML | N18904 | 001 | May 27, | 1983 | Apr | DISC |
|-----------|--|--------|-----|---------|------|-----|------|

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

| | | | | | | | | | |
|-----|----|---------------|------------|--------|-----|---------|------|-----|------|
| >D> | AT | @ BOCA PHARMA | EQ 1% BASE | N62930 | 001 | Jun 28, | 1989 | Apr | CAHN |
| >A> | | STIEFEL | EQ 1% BASE | N64108 | 001 | Sep 27, | 1996 | Jun | DISC |
| >A> | | @ | EQ 1% BASE | N64108 | 001 | Sep 27, | 1996 | Jun | DISC |

CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

CLOBETASOL PROPIONATE

| | | | | | | | | | |
|-----|----------------|--------------------|--------|--------|---------|---------|------|------|------|
| AB | PERRIGO ISRAEL | 0.05% | N77763 | 001 | Mar 10, | 2008 | Feb | NEWA | |
| >A> | AB | OLUX CONNETHICS | 0.05% | N21142 | 001 | May 26, | 2000 | Jun | CAHN |

AEROSOL, FOAM; TOPICAL

OLUX

| | | | | | | | | |
|--------------------------|-----|------------|-----------------------------------|--------|--------|--------------|--------------|----------|
| AB | + | CONNNETICS | 0.05% | N21142 | 001 | May 26, 2000 | Feb | CFTG |
| >D> | AB | + | STIEFEL LABS INC | 0.05% | N21142 | 001 | May 26, 2000 | JUN CAHN |
| <u>CREAM; TOPICAL</u> | | | | | | | | |
| | | | CLOBETASOL PROPIONATE | | | | | |
| >D> | AB1 | | STIEFEL | 0.05% | N75338 | 001 | Feb 09, 2001 | JUN DISC |
| >A> | | @ | | 0.05% | N75338 | 001 | Feb 09, 2001 | JUN DISC |
| | | | CLOBETASOL PROPIONATE (EMOLLIENT) | | | | | |
| >D> | AB2 | | STIEFEL | 0.05% | N75733 | 001 | Aug 22, 2001 | JUN DISC |
| >A> | | @ | | 0.05% | N75733 | 001 | Aug 22, 2001 | JUN DISC |
| <u>OINTMENT; TOPICAL</u> | | | | | | | | |
| | | | CLOBETASOL PROPIONATE | | | | | |
| >D> | AB | | STIEFEL | 0.05% | N75057 | 001 | Aug 12, 1998 | JUN DISC |
| >A> | | @ | | 0.05% | N75057 | 001 | Aug 12, 1998 | JUN DISC |

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

@ BANNER PHARMACAPS

500MG

N73396 001 Mar 20, 1992 May DISC

+ USL PHARMA

500MG

N70531 001 Jun 16, 1986 May CTEC

CLOPIDOGREL BISULFATE

TABLET; ORAL

CLOPIDOGREL BISULFATE

AB DR REDDYS LABS INC EQ 75MG BASE

N76273 001 Jan 14, 2008 Jan NEWA

CLOTRIMAZOLE

SOLUTION; TOPICAL

MYCELEX

| | | | | | | | | |
|-----------------------------|----|---|----------------|------|--------|-----|--------------|----------|
| >A> | AT | + | BAYER HLTHCARE | 1% | N18181 | 001 | | JUN CAHN |
| >D> | AT | + | BAYER PHARMS | 1% | N18181 | 001 | | JUN CAHN |
| <u>TROCHE/LOZENGE; ORAL</u> | | | | | | | | |
| | | | MYCELEX | | | | | |
| >A> | AB | + | BAYER HLTHCARE | 10MG | N18713 | 001 | Jun 17, 1983 | JUN CAHN |
| >D> | AB | + | BAYER PHARMS | 10MG | N18713 | 001 | Jun 17, 1983 | JUN CAHN |

CLOZAPINE

TABLET; ORAL

CLOZAPINE

@ TEVA

25MG

N75162 001 Apr 26, 2005 Mar DISC

@

100MG

N75162 002 Apr 26, 2005 Mar DISC

TABLET, ORALLY DISINTEGRATING; ORAL

FAZACLO ODT

| | | | | | | | | |
|-----|--|---|------------------|------|--------|-----|--------------|----------|
| >D> | | | AZUR PHARMA INTL | 50MG | N21590 | 003 | Jun 03, 2005 | JUN DISC |
| >A> | | @ | | 50MG | N21590 | 003 | Jun 03, 2005 | JUN DISC |

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIACIN-C

| | | | | | | |
|------------------------|---|--------|-----|--------------|-----|------|
| + ACTAVIS MID ATLANTIC | 10MG/5ML;30MG/5ML;1.25MG/5ML | N88704 | 001 | Mar 22, 1985 | Feb | CRLD |
| | TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE PHOSPHATE | | | | | |
| @ MORTON GROVE | 10MG/5ML;30MG/5ML;1.25MG/5ML | N88833 | 001 | Nov 16, 1984 | Feb | DISC |

COLCHICINE; PROBENECID

TABLET; ORAL
COL-PROBENECID
AB + WATSON LABS 0.5MG;500MG N84279 001 Apr CTEC
PROBENECID AND COLCHICINE
AB CONCORD LABS NJ 0.5MG;500MG N40618 001 May 13, 2008 Apr NEWA

COLISTIMETHATE

INJECTABLE; INJECTION
COLISTIMETHATE
AP APP PHARMS EQ 150MG BASE/VIAL N65364 001 Apr 17, 2008 Mar NEWA

COSYNTROPIN

SOLUTION; INTRAVENOUS
COSYNTROPIN
SANDOZ 0.25MG/ML (0.25MG/ML) N22028 001 Feb 21, 2008 Feb NEWA

CROMOLYN SODIUM

SOLUTION; INHALATION
CROMOLYN SODIUM
AN + IVAX PHARMS 10MG/ML N75271 001 Jan 18, 2000 May CRLD
INTAL
@ KING PHARMS 10MG/ML N18596 001 May 28, 1982 May DISC

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HYDROCHLORIDE
AB AMNEAL PHARM 10MG N78218 001 Apr 18, 2008 Mar NEWA
AB RANBAXY 5MG N78722 001 May 12, 2008 Apr NEWA
AB 7.5MG N78722 002 May 12, 2008 Apr NEWA
AB 10MG N78722 003 May 12, 2008 Apr NEWA
@ SANDOZ 10MG N73683 001 Feb 26, 1993 Feb DISC
AB WATSON LABS 7.5MG N71611 003 Feb 03, 2006 Apr CTEC
@ 10MG N73143 001 Nov 27, 1991 Feb DISC
@ 10MG N74436 001 Nov 30, 1994 Feb DISC

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
CYCLOPHOSPHAMIDE
@ BAXTER HLTHCARE 100MG/VIAL N88371 001 Jul 03, 1986 Jan DISC
@ 200MG/VIAL N88372 001 Jul 03, 1986 Jan DISC
AP @ 500MG/VIAL N40745 001 May 21, 2008 May NEWA
@ 500MG/VIAL N88373 001 Jul 03, 1986 Jan DISC
AP 1GM/VIAL N40745 002 May 21, 2008 May NEWA
@ 1GM/VIAL N88374 001 Sep 24, 1986 Jan DISC
AP 2GM/VIAL N40745 003 May 21, 2008 May NEWA

LYOPHILIZED CYTOXAN
+ BRISTOL MYERS SQUIBB 100MG/VIAL N12142 006 Dec 05, 1985 Jan CTEC
+ 200MG/VIAL N12142 007 Dec 10, 1985 Jan CTEC
AP + 500MG/VIAL N12142 008 Jan 04, 1984 May CFTG
+ 500MG/VIAL N12142 008 Jan 04, 1984 Jan CTEC
AP + 1GM/VIAL N12142 010 Sep 24, 1985 May CFTG
+ 1GM/VIAL N12142 010 Sep 24, 1985 Jan CTEC
AP + 2GM/VIAL N12142 009 Dec 10, 1984 May CFTG
+ 2GM/VIAL N12142 009 Dec 10, 1984 Jan CTEC

INJECTABLE; INJECTION

NEOSAR

| | | | | | |
|-------------------|------------|------------|--------------|-----|------|
| @ TEVA PARENTERAL | 100MG/VIAL | N87442 001 | Feb 16, 1982 | Jan | DISC |
| @ | 200MG/VIAL | N87442 002 | Feb 16, 1982 | Jan | DISC |
| @ | 500MG/VIAL | N87442 003 | Feb 16, 1982 | Jan | DISC |
| @ | 1GM/VIAL | N87442 004 | Jul 08, 1983 | Jan | DISC |
| @ | 2GM/VIAL | N87442 005 | Mar 30, 1989 | Jan | DISC |

TABLET; ORAL

CYCLOPHOSPHAMIDE

| | | | | | |
|------------------------|------|------------|--------------|-----|------|
| ROXANE | 25MG | N40032 001 | Aug 17, 1999 | Jan | CTEC |
| + | 50MG | N40032 002 | Aug 17, 1999 | Jan | CRLD |
| CYTOXAN | | | | | |
| @ BRISTOL MYERS SQUIBB | 25MG | N12141 002 | | Jan | DISC |
| @ | 50MG | N12141 001 | | Jan | DISC |

CYTARABINEINJECTABLE; INJECTION

CYTARABINE

| | | | | | | | |
|-----|----|---------------|----------|------------|--------------|-----|------|
| >D> | + | ABRAXIS PHARM | 100MG/ML | N76512 001 | Jan 15, 2004 | Jun | CTEC |
| >A> | AP | + | 100MG/ML | N76512 001 | Jan 15, 2004 | Jun | CTEC |
| >D> | | @ HOSPIRA | 100MG/ML | N75383 001 | Nov 22, 1999 | Jun | CMFD |
| >A> | AP | | 100MG/ML | N75383 001 | Nov 22, 1999 | Jun | CMFD |

DACARBAZINEINJECTABLE; INJECTION

DTIC-DOME

| | | | | | | | |
|-----|----|---|----------------|------------|------------|--|----------|
| >A> | AP | + | BAYER HLTHCARE | 100MG/VIAL | N17575 001 | | JUN CAHN |
| >A> | AP | + | | 200MG/VIAL | N17575 002 | | JUN CAHN |
| >D> | AP | + | BAYER PHARMS | 100MG/VIAL | N17575 001 | | JUN CAHN |
| >D> | AP | + | | 200MG/VIAL | N17575 002 | | JUN CAHN |

DALTEPARIN SODIUMINJECTABLE; INJECTION

FRAGMIN

| | | | | | | | |
|-----|--|------------------------|-----------------|------------|--------------|-----|------|
| >A> | | @ EISAI MEDCL RES | 7,500 IU/0.75ML | N20287 008 | Apr 04, 2002 | Jun | CAHN |
| >D> | | @ PHARMACIA AND UPJOHN | 7,500 IU/0.75ML | N20287 008 | Apr 04, 2002 | Jun | CAHN |

INJECTABLE; SUBCUTANEOUS

FRAGMIN

| | | | | | | | |
|-----|---|----------------------|-------------------------------|------------|--------------|-----|------|
| >A> | | EISAI MEDCL RES | 2,500IU/0.2ML (12,500IU/ML) | N20287 001 | Dec 22, 1994 | Jun | CAHN |
| >A> | | | 5,000IU/0.2ML (25,000IU/ML) | N20287 003 | Mar 18, 1996 | Jun | CAHN |
| >A> | | | 7,500IU/0.3ML (25,000IU/ML) | N20287 005 | Apr 04, 2002 | Jun | CAHN |
| >A> | | | 10,000IU/ML (10,000IU/ML) | N20287 004 | Jan 30, 1998 | Jun | CAHN |
| >A> | | | 10,000IU/0.4ML (25,000IU/ML) | N20287 002 | May 01, 2007 | Jun | CAHN |
| >A> | | | 12,500IU/0.5ML (25,000IU/ML) | N20287 009 | May 01, 2007 | Jun | CAHN |
| >A> | | | 15,000IU/0.6ML (25,000IU/ML) | N20287 010 | May 01, 2007 | Jun | CAHN |
| >A> | | | 18,000IU/0.72ML (25,000IU/ML) | N20287 011 | May 01, 2007 | Jun | CAHN |
| >A> | + | | 95,000IU/3.8ML(25,000IU/ML) | N20287 006 | Apr 04, 2002 | Jun | CAHN |
| >A> | | | 95,000IU/9.5ML(10,000IU/ML) | N20287 007 | Apr 04, 2002 | Jun | CAHN |
| >D> | | PHARMACIA AND UPJOHN | 2,500IU/0.2ML (12,500IU/ML) | N20287 001 | Dec 22, 1994 | Jun | CAHN |
| >D> | | | 5,000IU/0.2ML (25,000IU/ML) | N20287 003 | Mar 18, 1996 | Jun | CAHN |
| >D> | | | 7,500IU/0.3ML (25,000IU/ML) | N20287 005 | Apr 04, 2002 | Jun | CAHN |
| >D> | | | 10,000IU/0.4ML (25,000IU/ML) | N20287 002 | May 01, 2007 | Jun | CAHN |
| >D> | | | 10,000IU/ML (10,000IU/ML) | N20287 004 | Jan 30, 1998 | Jun | CAHN |
| >D> | | | 12,500IU/0.5ML (25,000IU/ML) | N20287 009 | May 01, 2007 | Jun | CAHN |
| >D> | | | 15,000IU/0.6ML (25,000IU/ML) | N20287 010 | May 01, 2007 | Jun | CAHN |
| >D> | | | 18,000IU/0.72ML (25,000IU/ML) | N20287 011 | May 01, 2007 | Jun | CAHN |

INJECTABLE; SUBCUTANEOUS

FRAGMIN

>D> + PHARMACIA AND UPJOHN 95,000IU/3.8ML(25,000IU/ML) N20287 006 Apr 04, 2002 Jun CAHN
 >D> + 95,000IU/9.5ML(10,000IU/ML) N20287 007 Apr 04, 2002 Jun CAHN

DARUNAVIR ETHANOLATE

TABLET; ORAL

PREZISTA

TIBOTEC

EQ 300MG BASE

N21976 001 Jun 23, 2006 Feb CRLD

+ EQ 600MG BASE

N21976 002 Feb 25, 2008 Feb NEWA

DASATINIB

TABLET; ORAL

SPRYCEL

BRISTOL MYERS SQUIBB 70MG

N21986 003 Jun 28, 2006 May CRLD

+ 100MG

N21986 004 May 30, 2008 May NEWA

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DEMECLOCYCLINE HYDROCHLORIDE

AB AMNEAL PHARM 150MG N65425 001 Feb 27, 2008 Feb NEWA
 AB 300MG N65425 002 Feb 27, 2008 Feb NEWA

DESMOPRESSIN ACETATE

TABLET; ORAL

DESMOPRESSIN ACETATE

FERRING 0.1MG

N21795 001 May 08, 2008 May NEWA

+ 0.2MG

N21795 002 May 08, 2008 May NEWA

DESOGESTREL; ETHINYLL ESTRADIOL

TABLET; ORAL-21

ORTHO-CEPT

>A> @ ORTHO MCNEIL 0.15MG;0.03MG N20301 001 Dec 14, 1992 Jun CAHN
 >D> @ ORTHO MCNEIL PHARM 0.15MG;0.03MG N20301 001 Dec 14, 1992 Jun CAHN

TABLET; ORAL-28

ORTHO-CEPT

>A> AB + ORTHO MCNEIL 0.15MG;0.03MG N20301 002 Dec 14, 1992 Jun CAHN
 >D> AB + ORTHO MCNEIL PHARM 0.15MG;0.03MG N20301 002 Dec 14, 1992 Jun CAHN

DESVENLAFAKINE SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

PRISTIQ

WYETH PHARMS INC EQ 50MG BASE

N21992 001 Feb 29, 2008 Feb NEWA

+ EQ 100MG BASE

N21992 002 Feb 29, 2008 Feb NEWA

DEXAMETHASONE

ELIXIR; ORAL

DEXAMETHASONE

AA + MORTON GROVE 0.5MG/5ML N88254 001 Jul 27, 1983 Feb CTNA

TABLET; ORAL

DEXAMETHASONE

@ PVT FORM 0.75MG

N83420 001 Apr CAHN

DEXCHLORPHENIRAMINE MALEATE

SYRUP; ORAL
 DEXCHLORPHENIRAMINE MALEATE
 + MORTON GROVE 2MG/5ML N88251 001 Mar 23, 1984 Feb CTNA
 TABLET; ORAL
 DEXCHLORPHENIRAMINE MALEATE
 @ PLIVA 2MG N88682 001 Jan 17, 1986 Feb DISC

DEXTROAMPHETAMINE SULFATE

SOLUTION; ORAL
 DEXTROAMPHETAMINE SULFATE
 + OUTLOOK PHARMS 5MG/5ML N40776 001 Jan 29, 2008 Jan NEWA

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION
 HYPaque
 @ GE HEALTHCARE 60% N16403 001 May DISC
 RENO-60
 + BRACCO 60% N10040 016 May CTEC
 SOLUTION; URETHRAL
 CYSTOGRAFIN
 BRACCO 30% N10040 018 May CTEC
 HYPAQUE-CYSTO
 @ GE HEALTHCARE 30% N16403 003 May DISC

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
 HYPaque-76
 @ GE HEALTHCARE 66%;10% N86505 001 May DISC
 >D> RENOCAL-76
 >D> AP BRACCO 66%;10% N89347 001 Jun 01, 1988 Jun DISC
 >A> @ 66%;10% N89347 001 Jun 01, 1988 Jun DISC

DIATRIZOATE SODIUM

INJECTABLE; INJECTION
 HYPaque
 @ GE HEALTHCARE 50% N09561 001 May DISC

DIAZEPAM

INJECTABLE; INJECTION
 DIAZEPAM
 @ MARSAM PHARMS LLC 5MG/ML N72397 001 Jan 29, 1993 Feb DISC

DICHLORPHENAMIDE

TABLET; ORAL
 DARANIDE
 @ TARO 50MG N11366 001 May CAHN

DICLOFENAC SODIUM

GEL; TOPICAL
 SOLARAZE
 + NYCOMED US 3% N21005 001 Oct 16, 2000 Feb CAHN
 SOLUTION/DROPS; OPHTHALMIC
 DICLOFENAC SODIUM
 AT AKORN 0.1% N77845 001 Apr 17, 2008 Mar NEWA

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

AT ALCON 0.1% N78031 001 Feb 06, 2008 Jan NEWA

TABLET, DELAYED RELEASE; ORAL

DICLOFENAC SODIUM

| | | |
|---------------|------|----------------------------------|
| >D> AB ROXANE | 25MG | N74391 001 Jun 29, 1995 Jun DISC |
| >A> @ | 25MG | N74391 001 Jun 29, 1995 Jun DISC |
| >D> AB | 50MG | N74391 002 Jun 29, 1995 Jun DISC |
| >A> @ | 50MG | N74391 002 Jun 29, 1995 Jun DISC |
| >D> AB | 75MG | N74391 003 Jun 29, 1995 Jun DISC |
| >A> @ | 75MG | N74391 003 Jun 29, 1995 Jun DISC |

DICLOXACILLIN SODIUMFOR SUSPENSION; ORAL

DICLOXACILLIN SODIUM

@ APOTHECON EQ 62.5MG BASE/5ML

N61455 001 Jan DISC

DIDANOSINE

| | | |
|----------------------------|-------|----------------------------------|
| >D> TABLET, CHEWABLE; ORAL | | |
| >D> VIDEX | | |
| >D> BRISTOL MYERS SQUIBB | 25MG | N20154 002 Oct 09, 1991 Jun DISC |
| >A> @ | 25MG | N20154 002 Oct 09, 1991 Jun DISC |
| >D> | 50MG | N20154 003 Oct 09, 1991 Jun DISC |
| >A> @ | 50MG | N20154 003 Oct 09, 1991 Jun DISC |
| >D> | 100MG | N20154 004 Oct 09, 1991 Jun DISC |
| >A> @ | 100MG | N20154 004 Oct 09, 1991 Jun DISC |
| >D> | 150MG | N20154 005 Oct 09, 1991 Jun DISC |
| >A> @ | 150MG | N20154 005 Oct 09, 1991 Jun DISC |
| >D> + | 200MG | N20154 006 Oct 28, 1999 Jun DISC |
| >A> @ | 200MG | N20154 006 Oct 28, 1999 Jun DISC |

DIFLUNISALTABLET; ORAL

DIFLUNISAL

| | | |
|------------------|-------|----------------------------------|
| AB TEVA | 500MG | N73673 001 Jul 31, 1992 May CRLD |
| AB + WATSON LABS | 500MG | N74400 002 Jul 17, 1997 May CRLD |

DIFLUPREDNATEEMULSION; OPHTHALMIC

DUREZOL

| | | |
|---------------------|-------|----------------------------------|
| >A> + SIRION THERAP | 0.05% | N22212 001 Jun 23, 2008 Jun NEWA |
|---------------------|-------|----------------------------------|

DIGOXININJECTABLE; INJECTION

DIGOXIN PEDIATRIC

@ HOSPIRA

0.1MG/ML

N40092 001 Apr 25, 1996 Apr DISC

LANOXIN PEDIATRIC

+ GLAXOSMITHKLINE

0.1MG/ML

N09330 004 Apr CTEC

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

| | | |
|-------------|-------|----------------------------------|
| AB3 BIOVAIL | 300MG | N20062 004 Dec 27, 1991 May CRLD |
|-------------|-------|----------------------------------|

INJECTABLE; INJECTION

CARDIZEM

@ BIOVAIL LABS INTL

5MG/ML

N20027 001 Oct 24, 1991 May DISC

INJECTABLE; INJECTION

| | | | | | | |
|-------------------------|-----------|--|--------|-----|--------------|----------|
| CARDIZEM | | | | | | |
| @ BIOVAIL LABS INTL | 25MG/VIAL | | N20027 | 003 | Aug 18, 1995 | May DISC |
| DILTIAZEM HYDROCHLORIDE | | | | | | |
| @ HOSPIRA | 5MG/ML | | N75004 | 001 | Feb 16, 2000 | Feb DISC |

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | | | |
|-------------------------------|------|--|--------|-----|--------------|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE | | | | | | |
| @ MUTUAL PHARM | 25MG | | N84506 | 001 | Feb | DISC |
| @ | 25MG | | N89488 | 001 | Jan 02, 1987 | Feb DISC |
| @ PVT FORM | 25MG | | N83027 | 001 | | Apr CAHN |
| @ | 50MG | | N83027 | 002 | | Apr CAHN |

ELIXIR; ORAL

| | | | | | | |
|-------------------------------|------------|--|--------|-----|--|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE | | | | | | |
| @ PVT FORM | 12.5MG/5ML | | N85287 | 001 | | Apr CAHN |

DIPYRIDAMOLE

TABLET; ORAL

| | | | | | | |
|-------------------------|------|--|--------|-----|--------------|----------|
| DIPYRIDAMOLE | | | | | | |
| AB LANNETT | 25MG | | N40898 | 001 | Apr 23, 2008 | Apr NEWA |
| AB | 50MG | | N40898 | 002 | Apr 23, 2008 | Apr NEWA |
| AB | 75MG | | N40898 | 003 | Apr 23, 2008 | Apr NEWA |
| AB ZYDUS PHARMS USA INC | 25MG | | N40874 | 001 | Jan 28, 2008 | Jan NEWA |
| AB | 50MG | | N40874 | 002 | Jan 28, 2008 | Jan NEWA |
| AB | 75MG | | N40874 | 003 | Jan 28, 2008 | Jan NEWA |

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | | |
|--------------------------|-------------------|--|--------|-----|--------------|----------|
| DOBUTAMINE HYDROCHLORIDE | | | | | | |
| @ MARSAM PHARMS LLC | EQ 12.5MG BASE/ML | | N74995 | 001 | Mar 31, 1998 | Feb DISC |

DONEPEZIL HYDROCHLORIDE

TABLET; ORAL

| | | | | | | |
|-------------------------|------|--|--------|-----|--------------|----------|
| ARICEPT | | | | | | |
| AB EISAI MEDCL RES | 5MG | | N20690 | 002 | Nov 25, 1996 | Apr CFTG |
| AB + | 10MG | | N20690 | 001 | Nov 25, 1996 | Apr CFTG |
| DONEPEZIL HYDROCHLORIDE | | | | | | |
| AB TEVA | 5MG | | N77344 | 001 | Apr 28, 2008 | Apr NEWA |
| AB | 10MG | | N77344 | 002 | Apr 28, 2008 | Apr NEWA |

DOXAZOSIN MESYLATE

TABLET; ORAL

| | | | | | | |
|--------------------|-------------|--|--------|-----|--------------|----------|
| DOXAZOSIN MESYLATE | | | | | | |
| @ GENPHARM | EQ 1MG BASE | | N75466 | 001 | Oct 18, 2000 | May DISC |
| @ | EQ 2MG BASE | | N75466 | 002 | Oct 18, 2000 | May DISC |
| @ | EQ 4MG BASE | | N75466 | 003 | Oct 18, 2000 | May DISC |
| @ | EQ 8MG BASE | | N75466 | 004 | Oct 18, 2000 | May DISC |

DOXE PIN HYDROCHLORIDE

CREAM; TOPICAL

| | | | | | | |
|--------------|----|--|--------|-----|--------------|----------|
| ZONALON | | | | | | |
| + NYCOMED US | 5% | | N20126 | 001 | Apr 01, 1994 | Feb CAHN |

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION

DOXIL

| | | | | | | | | | |
|-----|---|---------------|--------------------|--------|-----|---------|------|-----|------|
| >D> | + | ALZA | 2MG/ML | N50718 | 001 | Nov 17, | 1995 | Jun | CPOT |
| >A> | + | ORTHO BIOTECH | 20MG/10ML (2MG/ML) | N50718 | 001 | Nov 17, | 1995 | Jun | CPOT |
| >A> | + | | 50MG/25ML (2MG/ML) | N50718 | 002 | Jun 13, | 2000 | Jun | NEWA |

DOXYCYCLINE

CAPSULE, DELAYED RELEASE; ORAL

ORACEA

+ GALDERMA LABS LP 40MG

N50805 001 May 26, 2006 Apr CAHN

FOR SUSPENSION; ORAL

>A> DOXYCYCLINE

>A> AB IVAX PHARMS

EQ 25MG BASE/5ML

N65454 001 Jul 16, 2008 Jun NEWA

VIBRAMYCIN

>D> + PFIZER

EQ 25MG BASE/5ML

N50006 001 Jun CTEC

>A> AB +

EQ 25MG BASE/5ML

N50006 001 Jun CTEC

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

@ PVT FORM EQ 100MG BASE

N62631 002 Jul 24, 1986 Apr CAHN

TABLET; ORAL

PERIOSTAT

AB + GALDERMA LABS LP EQ 20MG BASE

N50783 001 Feb 02, 2001 Apr CAHN

TABLET, DELAYED RELEASE; ORAL

DORYX

>D> + MAYNE PHARMA INTL

EQ 100MG BASE

N50795 002 May 06, 2005 Jun CRLD

>A>

EQ 100MG BASE

N50795 002 May 06, 2005 Jun CRLD

>A> +

EQ 150MG BASE

N50795 003 Jun 20, 2008 Jun NEWA

DRONABINOL

CAPSULE; ORAL

DRONABINOL

>A> AB PAR PHARM

2.5MG

N78292 001 Jun 27, 2008 Jun NEWA

>A> AB

5MG

N78292 002 Jun 27, 2008 Jun NEWA

>A> AB

10MG

N78292 003 Jun 27, 2008 Jun NEWA

MARINOL

>D> UNIMED

2.5MG

N18651 001 May 31, 1985 Jun CFTG

>A> AB

2.5MG

N18651 001 May 31, 1985 Jun CFTG

>D> +

5MG

N18651 002 May 31, 1985 Jun CFTG

>A> AB +

5MG

N18651 002 May 31, 1985 Jun CFTG

>D>

10MG

N18651 003 May 31, 1985 Jun CFTG

>A> AB

10MG

N18651 003 May 31, 1985 Jun CFTG

DROSPIRENONE; ETHINYLN ESTRADIOL

TABLET; ORAL-28

DROSPIRENONE AND ETHINYLN ESTRADIOL

AB BARR 3MG; 0.03MG

N77527 001 May 09, 2008 Apr NEWA

YASMIN

AB + BAYER HLTHCARE 3MG; 0.03MG

N21098 001 May 11, 2001 Apr CFTG

DYPHYLLINE

| | | | | |
|--------------|---------------------|-------|------------|----------|
| TABLET; ORAL | | | | |
| LUFYLLIN | | | | |
| >A> | MEDA PHARMS | 200MG | N84566 001 | Jun CAHN |
| >A> | + | 400MG | N84566 002 | Jun CAHN |
| >D> | MEDPOINTE PHARM HLC | 200MG | N84566 001 | Jun CAHN |
| >D> | + | 400MG | N84566 002 | Jun CAHN |

ECONAZOLE NITRATE

| | | | | |
|-------------------|----|--|------------|-----------------------|
| CREAM; TOPICAL | | | | |
| SPECTAZOLE | | | | |
| @ ORTHONEUTROGENA | 1% | | N18751 001 | Dec 23, 1982 Feb CAHN |

EDROPHONIUM CHLORIDE

| | | | | |
|------------------------|---------|--|------------|-----------------------|
| INJECTABLE; INJECTION | | | | |
| ENLON | | | | |
| @ BAXTER HLTHCARE CORP | 10MG/ML | | N88873 001 | Aug 06, 1985 Feb DISC |

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

| | | | | |
|---|---|--------------|------------|-----------------------|
| INJECTABLE; INJECTION | | | | |
| LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE | | | | |
| @ HOSPIRA | 0.005MG/ML;1.5% | | N89650 001 | Jun 21, 1988 Apr DISC |
| AP | 0.01MG/ML;2% | | N78772 001 | May 12, 2008 Apr NEWA |
| AP | 0.02MG/ML;2% | | N78772 002 | May 12, 2008 Apr NEWA |
| XYLOCAINE W/ EPINEPHRINE | | | | |
| AP + DENTSPLY PHARM | 0.01MG/ML;2% | | N21381 001 | Apr CFTG |
| AP + | 0.02MG/ML;2% | | N21381 002 | Apr CFTG |
| >D> | SOLUTION; IONTOPHORESIS, TOPICAL | | | |
| >D> | LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE | | | |
| >D> | + EMPI | 0.01MG/ML;2% | N21486 001 | Oct 26, 2004 Jun DISC |
| >A> | @ | 0.01MG/ML;2% | N21486 001 | Oct 26, 2004 Jun DISC |

EPIRUBICIN HYDROCHLORIDE

| | | | | |
|---------------------------|------------|--|------------|-----------------------|
| INJECTABLE; IV (INFUSION) | | | | |
| EPIRUBICIN HYDROCHLORIDE | | | | |
| >D> + HOSPIRA | 200MG/VIAL | | N50807 002 | Sep 15, 2006 Jun DISC |
| >A> @ | 200MG/VIAL | | N50807 002 | Sep 15, 2006 Jun DISC |

EPOPROSTENOL SODIUM

| | | | | |
|-----------------------|--------------------|--|------------|-----------------------|
| INJECTABLE; INJECTION | | | | |
| EPOPROSTENOL SODIUM | | | | |
| >A> + GENERAMEDIX | EQ 1.5MG BASE/VIAL | | N22260 001 | Jun 27, 2008 Jun NEWA |
| AP TEVA PARENTERAL | EQ 0.5MG BASE/VIAL | | N78396 001 | Apr 23, 2008 Apr NEWA |
| AP | EQ 1.5MG BASE/VIAL | | N78396 002 | Apr 23, 2008 Apr NEWA |
| FLOLAN | | | | |
| AP + GLAXOSMITHKLINE | EQ 0.5MG BASE/VIAL | | N20444 001 | Sep 20, 1995 Apr CFTG |
| AP + | EQ 1.5MG BASE/VIAL | | N20444 002 | Sep 20, 1995 Apr CFTG |

ERYTHROMYCIN

| | | | | |
|-------------------------|----|--|------------|-----------------------|
| GEL; TOPICAL | | | | |
| E-GLADES | | | | |
| >D> AT GLADES PHARMS | 2% | | N65009 001 | Mar 18, 2002 Jun CAHN |
| >A> AT STIEFEL LABS INC | 2% | | N65009 001 | Mar 18, 2002 Jun CAHN |

SWAB; TOPICAL

ERYCETTE

@ ORTHONEUTROGENA 2%

N50594 001 Feb 15, 1985 Feb CAHN

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC

>D> @ BAXTER HLTHCARE CORP 100MG/ML
>A> @ 10MG/MLN19386 003 Dec 31, 1986 Jun CPOT
N19386 003 Aug 15, 1988 Jun CPOTESOMEPRAZOLE MAGNESIUM

FOR SUSPENSION, DELAYED RELEASE; ORAL

NEXIUM

ASTRAZENECA EQ 10MG BASE/PACKET

N22101 001 Feb 27, 2008 Feb NEWA

ESTRADIOL

GEL, METERED; TRANSDERMAL

ELESTRIN

+ BRADLEY PHARMS 0.06% (0.87GM/ACTIVATION)

N21813 001 Dec 15, 2006 Jan CTEC

+ NYCOMED US 0.06% (0.87GM/ACTIVATION)

N21813 001 Dec 15, 2006 Feb CAHN

ESTROGEL

+ ASCEND 0.06% (1.25GM/ACTIVATION)

N21166 002 Feb 09, 2004 Jan CTEC

ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

ACTIVELLA

AB + NOVO NORDISK INC 1MG;0.5MG
ESTRADIOL AND NORETHINDRONE ACETATE
AB BRECKENRIDGE PHARM 1MG;0.5MG

N20907 001 Nov 18, 1998 Mar CFTG

N78324 001 Apr 17, 2008 Mar NEWA

ESTROGENS, ESTERIFIED

TABLET; ORAL

ESTERIFIED ESTROGENS

@ PVT FORM 0.625MG

N83414 001 Apr CAHN

@ 1.25MG

N83765 001 Apr CAHN

@ 2.5MG

N85907 001 Apr CAHN

FEMOGEN

@ PVT FORM 0.625MG

N85076 001 Apr CAHN

@ 1.25MG

N85008 001 Apr CAHN

@ 2.5MG

N85007 001 Apr CAHN

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

MYAMBUTOL

AB STAT-TRADE 100MG
@ 200MG
AB 400MG
@ 500MG

N16320 001 Jan CAHN

N16320 002 Jan CAHN

N16320 003 Jan CAHN

N16320 004 Jan CAHN

ETHINYLEDIESTRADIOL; NORELGESTROMIN

FILM, EXTENDED RELEASE; TRANSDERMAL

ORTHO EVRA

>A> + ORTHO MCNEIL 0.02MG/24HR;0.15MG/24HR
>D> + ORTHO MCNEIL PHARM 0.02MG/24HR;0.15MG/24HR

N21180 001 Nov 20, 2001 Jun CAHN

N21180 001 Nov 20, 2001 Jun CAHN

ETHINYLY ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

ORTHO-NOVUM 10/11-21

| | | | | | | | |
|----------------------|----------------------|---|--------|-----|--------------|-----|------|
| >A> | @ ORTHO MCNEIL | 0.035MG, 0.035MG; 0.5MG, 1MG | N18354 | 001 | Jan 11, 1982 | Jun | CAHN |
| >D> | @ ORTHO MCNEIL PHARM | 0.035MG, 0.035MG; 0.5MG, 1MG | N18354 | 001 | Jan 11, 1982 | Jun | CAHN |
| ORTHO-NOVUM 7/7/7-21 | | | | | | | |
| >A> | @ ORTHO MCNEIL | 0.035MG, 0.035MG, 0.035MG; 0.5MG, 0.7 5MG, 1MG | N18985 | 001 | Apr 04, 1984 | Jun | CAHN |
| >D> | @ ORTHO MCNEIL PHARM | 0.035MG, 0.035MG, 0.035MG; 0.5MG, 0.7 5MG, 1MG | N18985 | 001 | Apr 04, 1984 | Jun | CAHN |

TABLET; ORAL-28

MODICON 28

| | | | | | | | |
|----------------------|----------------------|---|--------|-----|--------------|-----|------|
| >A> AB | ORTHO MCNEIL | 0.035MG; 0.5MG | N17735 | 001 | | Jun | CAHN |
| >D> AB | ORTHO MCNEIL PHARM | 0.035MG; 0.5MG | N17735 | 001 | | Jun | CAHN |
| ORTHO-NOVUM 1/35-28 | | | | | | | |
| >A> AB | + ORTHO MCNEIL | 0.035MG; 1MG | N17919 | 002 | | Jun | CAHN |
| >D> AB | + ORTHO MCNEIL PHARM | 0.035MG; 1MG | N17919 | 002 | | Jun | CAHN |
| ORTHO-NOVUM 10/11-28 | | | | | | | |
| >A> AB | + ORTHO MCNEIL | 0.035MG, 0.035MG; 0.5MG, 1MG | N18354 | 002 | Jan 11, 1982 | Jun | CAHN |
| >D> AB | + ORTHO MCNEIL PHARM | 0.035MG, 0.035MG; 0.5MG, 1MG | N18354 | 002 | Jan 11, 1982 | Jun | CAHN |
| ORTHO-NOVUM 7/7/7-28 | | | | | | | |
| >A> AB | + ORTHO MCNEIL | 0.035MG, 0.035MG, 0.035MG; 0.5MG, 0.7 5MG, 1MG | N18985 | 002 | Apr 04, 1984 | Jun | CAHN |
| >D> AB | + ORTHO MCNEIL PHARM | 0.035MG, 0.035MG, 0.035MG; 0.5MG, 0.7 5MG, 1MG | N18985 | 002 | Apr 04, 1984 | Jun | CAHN |

ETHINYLY ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

ORTHO TRI-CYCLEN LO

| | | | | | | | |
|-------|--------------------|--|--------|-----|--------------|-----|------|
| >A> + | ORTHO MCNEIL | 0.025MG, 0.025MG, 0.025MG; 0.18MG, 0. 215MG, 0.25MG | N21241 | 001 | Aug 22, 2002 | Jun | CAHN |
| >A> + | | 0.025MG, 0.025MG, 0.025MG; 0.18MG, 0. 215MG, 0.25MG | N21241 | 001 | Aug 22, 2002 | Jun | CAHN |
| >A> + | | 0.025MG, 0.025MG, 0.025MG; 0.18MG, 0. 215MG, 0.25MG | N21241 | 001 | Aug 22, 2002 | Jun | CAHN |
| >D> + | ORTHO MCNEIL PHARM | 0.025MG, 0.025MG, 0.025MG; 0.18MG, 0. 215MG, 0.25MG | N21241 | 001 | Aug 22, 2002 | Jun | CAHN |
| >D> + | | 0.025MG, 0.025MG, 0.025MG; 0.18MG, 0. 215MG, 0.25MG | N21241 | 001 | Aug 22, 2002 | Jun | CAHN |
| >D> + | | 0.025MG, 0.025MG, 0.025MG; 0.18MG, 0. 215MG, 0.25MG | N21241 | 001 | Aug 22, 2002 | Jun | CAHN |

ETHIONAMIDE

TABLET; ORAL

TRECATOR

| | | | | | | |
|--------------------|-------|--------|-----|--|-----|------|
| + WYETH PHARMS INC | 250MG | N13026 | 002 | | Apr | CTNA |
|--------------------|-------|--------|-----|--|-----|------|

ETHOSUXIMIDE

CAPSULE; ORAL

ETHOSUXIMIDE

| | | | | | | |
|------------------------|-------|--------|-----|--------------|-----|------|
| AB COVENANT PHARMA INC | 250MG | N40686 | 001 | May 28, 2008 | May | NEWA |
|------------------------|-------|--------|-----|--------------|-----|------|

ETRAVIRINE

TABLET; ORAL

INTELENCE

| | | | | | | |
|-----------|-------|--------|-----|--------------|-----|------|
| + TIBOTEC | 100MG | N22187 | 001 | Jan 18, 2008 | Jan | NEWA |
|-----------|-------|--------|-----|--------------|-----|------|

FAMOTIDINE

INJECTABLE; INJECTION

FAMOTIDINE

| | | | | | | | | | |
|-----|----|------------------------------|---------|--------|-----|---------|------|-----|------|
| >A> | AP | AKORN STRIDES | 10MG/ML | N78641 | 001 | Jun 25, | 2008 | Jun | NEWA |
| | | @ APOTEX INC | 10MG/ML | N75942 | 001 | Aug 02, | 2002 | Feb | DISC |
| | | @ HOSPIRA | 10MG/ML | N75905 | 001 | Nov 23, | 2001 | Feb | DISC |
| | | FAMOTIDINE PRESERVATIVE FREE | | | | | | | |
| >A> | AP | AKORN STRIDES | 10MG/ML | N78642 | 001 | Jun 25, | 2008 | Jun | NEWA |
| | | TABLET; ORAL | | | | | | | |
| | | FAMOTIDINE | | | | | | | |
| | | @ SANDOZ | 20MG | N75793 | 001 | Apr 16, | 2001 | Feb | DISC |
| | | @ | 40MG | N75793 | 002 | Apr 16, | 2001 | Feb | DISC |

FELBAMATE

SUSPENSION; ORAL

FELBATOL

| | | | | | | | | | |
|-----|---|--------------|-----------|--------|-----|---------|------|-----|------|
| >A> | + | MEDA PHARMS | 600MG/5ML | N20189 | 003 | Jul 29, | 1993 | Jun | CAHN |
| >D> | + | MEDPOINTE | 600MG/5ML | N20189 | 003 | Jul 29, | 1993 | Jun | CAHN |
| | | TABLET; ORAL | | | | | | | |
| | | FELBATOL | | | | | | | |
| >A> | | MEDA PHARMS | 400MG | N20189 | 001 | Jul 29, | 1993 | Jun | CAHN |
| >A> | + | | 600MG | N20189 | 002 | Jul 29, | 1993 | Jun | CAHN |
| >D> | | MEDPOINTE | 400MG | N20189 | 001 | Jul 29, | 1993 | Jun | CAHN |
| >D> | + | | 600MG | N20189 | 002 | Jul 29, | 1993 | Jun | CAHN |

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

FELODIPINE

| | | | | | | | | |
|----|-------|-------|--------|-----|---------|------|-----|------|
| AB | MYLAN | 2.5MG | N78855 | 001 | Apr 17, | 2008 | Mar | NEWA |
| AB | | 5MG | N78855 | 002 | Apr 17, | 2008 | Mar | NEWA |
| AB | | 10MG | N78855 | 003 | Apr 17, | 2008 | Mar | NEWA |

FENOFIBRATE

TABLET; ORAL

FENOFIBRATE

| | | | | | | | | |
|----|-------------------|-------|--------|-----|---------|------|-----|------|
| AB | IMPAX LABS | 54MG | N76509 | 001 | Mar 26, | 2008 | Mar | NEWA |
| AB | | 160MG | N76509 | 002 | Mar 26, | 2008 | Mar | NEWA |
| | SCIELE PHARMA INC | 40MG | N22118 | 001 | Aug 10, | 2007 | Apr | CAHN |
| | + | 120MG | N22118 | 002 | Aug 10, | 2007 | Apr | CAHN |

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

| | | | | | | | |
|-------------|---------------|--------|-----|---------|------|-----|------|
| @ PAR PHARM | EQ 200MG BASE | N72437 | 001 | Aug 22, | 1988 | May | DISC |
| @ | EQ 300MG BASE | N72438 | 001 | Aug 22, | 1988 | May | DISC |
| @ SANDOZ | EQ 200MG BASE | N72394 | 001 | Oct 17, | 1988 | May | DISC |
| @ | EQ 300MG BASE | N72395 | 001 | Oct 17, | 1988 | May | DISC |
| | | | | | | | |

NALFON

@ PEDINOL

EQ 300MG BASE

N17604 002 May DISC

NALFON 200

+ PEDINOL

EQ 200MG BASE

N17604 003 May CRLD

TABLET; ORAL

FENOPROFEN CALCIUM

@ WATSON LABS

EQ 600MG BASE

N72407 001 Aug 17, 1988 Feb DISC

@

EQ 600MG BASE

N72602 001 Oct 11, 1988 Feb DISC

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL

FEXOFENADINE HYDROCHLORIDE

| | | | |
|----|-------|------|----------------------------------|
| AB | MYLAN | 30MG | N77081 002 Apr 11, 2008 Mar NEWA |
| AB | | 60MG | N77081 003 Apr 11, 2008 Mar NEWA |

FLAVOXATE HYDROCHLORIDE

TABLET; ORAL

URISPAS

| | | | | | |
|-----|----|---|--------------------|-------|---------------------|
| >A> | AB | + | ORTHO MCNEIL | 100MG | N16769 001 Jun CAHN |
| >D> | AB | + | ORTHO MCNEIL PHARM | 100MG | N16769 001 Jun CAHN |

FLECAINIDE ACETATE

TABLET; ORAL

FLECAINIDE ACETATE

| | | | |
|----|--------------|-------|----------------------------------|
| AB | AMNEAL PHARM | 50MG | N75442 001 Jul 31, 2001 Feb CAHN |
| AB | | 100MG | N75442 002 Jul 31, 2001 Feb CAHN |
| AB | | 150MG | N75442 003 Jul 31, 2001 Feb CAHN |

FLUCONAZOLE

TABLET; ORAL

FLUCONAZOLE

| | | | | |
|-----|----|--------------------|-------|----------------------------------|
| >D> | AB | DR REDDYS LABS INC | 50MG | N76658 001 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 50MG | N76658 001 Jul 29, 2004 Jun CTEC |
| >D> | AB | | 100MG | N76658 002 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 100MG | N76658 002 Jul 29, 2004 Jun CTEC |
| >D> | AB | | 150MG | N76658 003 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 150MG | N76658 003 Jul 29, 2004 Jun CTEC |
| >D> | AB | | 200MG | N76658 004 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 200MG | N76658 004 Jul 29, 2004 Jun CTEC |
| >D> | AB | PLIVA | 50MG | N76424 001 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 50MG | N76424 001 Jul 29, 2004 Jun CTEC |
| >D> | AB | | 100MG | N76424 002 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 100MG | N76424 002 Jul 29, 2004 Jun CTEC |
| >D> | AB | | 150MG | N76424 003 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 150MG | N76424 003 Jul 29, 2004 Jun CTEC |
| >D> | AB | | 200MG | N76424 004 Jul 29, 2004 Jun CTEC |
| >A> | BX | | 200MG | N76424 004 Jul 29, 2004 Jun CTEC |
| >D> | AB | ROXANE | 50MG | N76213 001 Jul 29, 2004 Jun DISC |
| >A> | @ | | 50MG | N76213 001 Jul 29, 2004 Jun DISC |
| >D> | AB | | 100MG | N76213 002 Jul 29, 2004 Jun DISC |
| >A> | @ | | 100MG | N76213 002 Jul 29, 2004 Jun DISC |
| >D> | AB | | 150MG | N76213 003 Jul 29, 2004 Jun DISC |
| >A> | @ | | 150MG | N76213 003 Jul 29, 2004 Jun DISC |
| >D> | AB | | 200MG | N76213 004 Jul 29, 2004 Jun DISC |
| >A> | @ | | 200MG | N76213 004 Jul 29, 2004 Jun DISC |

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

| | | | |
|----|---------------|---------------------|----------------------------------|
| AP | AKORN STRIDES | 0.5MG/5ML(0.1MG/ML) | N78595 001 May 13, 2008 Apr NEWA |
| AP | | 1MG/10ML(0.1MG/ML) | N78595 002 May 13, 2008 Apr NEWA |

FLUOCINONIDE

| | | | | | | |
|-------------------|-------|--|--|--|------------|-----------------------|
| CREAM; TOPICAL | | | | | | |
| FLUOCINONIDE | | | | | | |
| @ TARO | 0.05% | | | | N71500 001 | Jun 10, 1987 Feb DISC |
| SOLUTION; TOPICAL | | | | | | |
| FLUOCINONIDE | | | | | | |
| @ TARO | 0.05% | | | | N72857 001 | Aug 02, 1989 Feb DISC |

FLUOROURACIL

| | | | | | | |
|-------------------------|----|--|--|--|------------|-----------------------|
| CREAM; TOPICAL | | | | | | |
| EFUDEX | | | | | | |
| AB + VALEANT PHARM INTL | 5% | | | | N16831 003 | Mar CFTG |
| FLUOROURACIL | | | | | | |
| AB SPEAR PHARMS | 5% | | | | N77524 001 | Apr 11, 2008 Mar NEWA |

FLUOXETINE HYDROCHLORIDE

| | | | | | | |
|--------------------------|--------------|--|--|--|------------|-----------------------|
| CAPSULE; ORAL | | | | | | |
| FLUOXETINE | | | | | | |
| AB AUROBINDO PHARMA | EQ 10MG BASE | | | | N78619 001 | Jan 31, 2008 Jan NEWA |
| AB | EQ 20MG BASE | | | | N78619 002 | Jan 31, 2008 Jan NEWA |
| AB | EQ 40MG BASE | | | | N78619 003 | Jan 31, 2008 Jan NEWA |
| AB WOCKHARDT | EQ 10MG BASE | | | | N78143 001 | Jan 16, 2008 Jan NEWA |
| AB | EQ 20MG BASE | | | | N78143 002 | Jan 16, 2008 Jan NEWA |
| AB | EQ 40MG BASE | | | | N78143 003 | Jan 16, 2008 Jan NEWA |
| FLUOXETINE HYDROCHLORIDE | | | | | | |
| AB1 ALPHAPHARM | EQ 10MG BASE | | | | N75577 001 | Jan 29, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N75577 002 | Jan 29, 2002 May CTEC |
| AB1 AUROBINDO PHARMA | EQ 10MG BASE | | | | N78619 001 | Jan 31, 2008 May CTEC |
| AB1 | EQ 20MG BASE | | | | N78619 002 | Jan 31, 2008 May CTEC |
| AB | EQ 40MG BASE | | | | N78619 003 | Jan 31, 2008 May CTNA |
| AB1 BARR | EQ 10MG BASE | | | | N74803 002 | Jan 30, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N74803 001 | Aug 02, 2001 May CTEC |
| AB | EQ 40MG BASE | | | | N76251 001 | May 18, 2005 May CTNA |
| AB1 CARLSBAD | EQ 10MG BASE | | | | N76022 001 | Jan 30, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N76022 002 | Jan 30, 2002 May CTEC |
| AB1 DR REDDYS LABS INC | EQ 10MG BASE | | | | N75465 001 | Jan 29, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N75465 002 | Jan 29, 2002 May CTEC |
| AB | EQ 40MG BASE | | | | N75465 003 | Aug 02, 2001 May CTNA |
| AB1 IVAX PHARMS | EQ 10MG BASE | | | | N75245 002 | Jan 31, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N75245 001 | Jan 31, 2002 May CTEC |
| AB | EQ 40MG BASE | | | | N75245 003 | Sep 28, 2004 May CTNA |
| AB1 MALLINCKRODT | EQ 10MG BASE | | | | N75658 001 | Jan 29, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N75658 002 | Jan 29, 2002 May CTEC |
| AB1 MYLAN | EQ 10MG BASE | | | | N75207 001 | Jan 30, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N75207 002 | Jan 30, 2002 May CTEC |
| AB | EQ 40MG BASE | | | | N75207 003 | May 25, 2007 May CTNA |
| AB1 PAR PHARM | EQ 10MG BASE | | | | N76922 001 | Dec 16, 2004 May CTEC |
| AB1 | EQ 20MG BASE | | | | N76922 002 | Dec 16, 2004 May CTEC |
| AB | EQ 40MG BASE | | | | N76922 003 | Dec 16, 2004 May CTNA |
| AB1 PLIVA | EQ 10MG BASE | | | | N76001 001 | Jan 29, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N76001 002 | Jan 29, 2002 May CTEC |
| AB1 RANBAXY | EQ 10MG BASE | | | | N76165 001 | Feb 01, 2002 May CTEC |
| AB1 | EQ 20MG BASE | | | | N76165 002 | Feb 01, 2002 May CTEC |
| AB | EQ 40MG BASE | | | | N76990 001 | Dec 13, 2004 May CTNA |
| AB1 RXELITE | EQ 10MG BASE | | | | N75464 001 | Jan 30, 2002 May CTEC |

CAPSULE; ORALFLUOXETINE HYDROCHLORIDE

| | | | | | | |
|-----|-----------|--------------|------------|--------------|-----|------|
| AB1 | RXELITE | EQ 20MG BASE | N75464 002 | Jan 30, 2002 | May | CTEC |
| AB1 | SANDOZ | EQ 10MG BASE | N75049 001 | Aug 02, 2001 | May | CTEC |
| AB1 | | EQ 10MG BASE | N75807 001 | Jan 29, 2002 | May | CTEC |
| AB1 | | EQ 20MG BASE | N75049 002 | Jan 29, 2002 | May | CTEC |
| AB1 | | EQ 20MG BASE | N75807 002 | Jan 29, 2002 | May | CTEC |
| AB1 | TEVA | EQ 10MG BASE | N75452 001 | Jan 29, 2002 | May | CTEC |
| AB2 | | EQ 10MG BASE | N76287 001 | May 20, 2008 | May | NEWA |
| AB1 | | EQ 20MG BASE | N75452 002 | Jan 29, 2002 | May | CTEC |
| AB2 | | EQ 20MG BASE | N76287 002 | May 20, 2008 | May | NEWA |
| AB | | EQ 40MG BASE | N75452 003 | Jan 29, 2002 | May | CTNA |
| AB1 | WOCKHARDT | EQ 10MG BASE | N78143 001 | Jan 16, 2008 | May | CTEC |
| AB1 | | EQ 20MG BASE | N78143 002 | Jan 16, 2008 | May | CTEC |
| AB | | EQ 40MG BASE | N78143 003 | Jan 16, 2008 | May | CTNA |
| | PROZAC | | | | | |
| AB1 | LILLY | EQ 10MG BASE | N18936 006 | Dec 23, 1992 | May | CTEC |
| AB1 | | EQ 20MG BASE | N18936 001 | Dec 29, 1987 | May | CTEC |
| | SARAFEM | | | | | |
| AB2 | LILLY | EQ 10MG BASE | N18936 007 | Jul 06, 2000 | May | CFTG |
| AB2 | + | EQ 20MG BASE | N18936 008 | Jul 06, 2000 | May | CFTG |

FLUOXYMESTERONETABLET; ORALFLUOXYMESTERONE

| | | | | | | | |
|-----|----|----------------------|------|------------|--------------|-----|------|
| >D> | BP | USL PHARMA | 10MG | N88342 001 | Oct 21, 1983 | Jun | CRLD |
| >A> | + | | 10MG | N88342 001 | Oct 21, 1983 | Jun | CRLD |
| >D> | | HALOTESTIN | | | | | |
| >D> | | PHARMACIA AND UPJOHN | 2MG | N10611 002 | | Jun | DISC |
| >A> | @ | | 2MG | N10611 002 | | Jun | DISC |
| >D> | | | 5MG | N10611 006 | | Jun | DISC |
| >A> | @ | | 5MG | N10611 006 | | Jun | DISC |
| >D> | BP | + | 10MG | N10611 010 | | Jun | DISC |
| >A> | @ | | 10MG | N10611 010 | | Jun | DISC |

FLUTICASONE PROPIONATESPRAY, METERED; NASALFLUTICASONE PROPIONATE

| | | | | | | |
|----|----------------|--------------|------------|--------------|-----|------|
| AB | HI TECH PHARMA | 0.05MG/SPRAY | N77570 001 | Jan 16, 2008 | Jan | NEWA |
|----|----------------|--------------|------------|--------------|-----|------|

FLUVOXAMINE MALEATECAPSULE, EXTENDED RELEASE; ORALLUVOX CR

| | | | | | | | |
|-----|---|--------|-------|------------|--------------|-----|------|
| >A> | | JAZZ | 100MG | N22033 001 | Feb 28, 2008 | Jun | CAHN |
| >A> | + | | 150MG | N22033 002 | Feb 28, 2008 | Jun | CAHN |
| >D> | | SOLVAY | 100MG | N22033 001 | Feb 28, 2008 | Jun | CAHN |
| | | | 100MG | N22033 001 | Feb 28, 2008 | Feb | NEWA |
| >D> | + | | 150MG | N22033 002 | Feb 28, 2008 | Jun | CAHN |
| | + | | 150MG | N22033 002 | Feb 28, 2008 | Feb | NEWA |

TABLET; ORALFLUVOXAMINE MALEATE

@ SYNTHON PHARMS

25MG

N75899 001 Jan 17, 2001 May DISC

@

50MG

N75899 002 Jan 17, 2001 May DISC

@

100MG

N75899 003 Jan 17, 2001 May DISC

LUVOX

| | | | | | | |
|----|------|------|------------|--------------|-----|------|
| AB | JAZZ | 25MG | N21519 001 | Dec 20, 2007 | Apr | CAHN |
|----|------|------|------------|--------------|-----|------|

TABLET; ORAL

LUVOX

| | | | |
|----|------|-------|----------------------------------|
| AB | JAZZ | 50MG | N21519 002 Dec 20, 2007 Apr CAHN |
| AB | | 100MG | N21519 003 Dec 20, 2007 Apr CAHN |

FOMEPIZOLE

INJECTABLE; INJECTION

FOMEPIZOLE

| | | | |
|----|---------------|----------------------|----------------------------------|
| AP | NAVINTA LLC | 1.5GM/1.5ML (1GM/ML) | N78537 001 Mar 06, 2008 Feb NEWA |
| AP | SYNERX PHARMA | 1.5GM/1.5ML (1GM/ML) | N78639 001 Mar 03, 2008 Feb NEWA |

FOSAPREPITANT DIMEGLUMINE

POWDER; INTRAVENOUS

EMEND

+ MERCK AND CO INC

EQ 115MG BASE/VIAL

N22023 001 Jan 25, 2008 Jan NEWA

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

| | | | |
|----|---------------|-------------------------|----------------------------------|
| AP | AKORN STRIDES | EQ 50MG PNENYTOIN NA/ML | N78476 001 Mar 18, 2008 Mar NEWA |
| AP | SUN PHARM IND | EQ 50MG PHENYTOIN NA/ML | N78417 001 Mar 18, 2008 Mar NEWA |

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

@ HOSPIRA

10MG/ML

N74337 001 Oct 31, 1994 Apr DISC

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

| | | | |
|----|-----------------|-------|----------------------------------|
| AB | AUROBINDO PHARM | 100MG | N78787 001 Jan 31, 2008 Jan NEWA |
| AB | | 300MG | N78787 002 Jan 31, 2008 Jan NEWA |
| AB | | 400MG | N78787 003 Jan 31, 2008 Jan NEWA |
| | @ MUTUAL PHARM | 100MG | N76537 001 Jun 30, 2005 Mar DISC |
| | @ | 300MG | N76537 002 Jun 30, 2005 Mar DISC |
| | @ | 400MG | N76537 003 Jun 30, 2005 Mar DISC |

GADODIAMIDE

INJECTABLE; INJECTION

OMNISCAN

@ GE HEALTHCARE

14.35GM/50ML(287MG/ML)

N22066 001 Sep 05, 2007 May DISC

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

RAZADYNE ER

| | | | |
|-----|----------------|--------------|----------------------------------|
| >D> | + JANSSEN | EQ 8MG BASE | N21615 001 Apr 01, 2005 Jun CAHN |
| >D> | | EQ 16MG BASE | N21615 002 Apr 01, 2005 Jun CAHN |
| >D> | | EQ 24MG BASE | N21615 003 Apr 01, 2005 Jun CAHN |
| >A> | + ORTHO MCNEIL | EQ 8MG BASE | N21615 001 Apr 01, 2005 Jun CAHN |
| >A> | | EQ 16MG BASE | N21615 002 Apr 01, 2005 Jun CAHN |
| >A> | | EQ 24MG BASE | N21615 003 Apr 01, 2005 Jun CAHN |

SOLUTION; ORAL

RAZADYNE

| | | | |
|-----|------------------|--------|----------------------------------|
| >D> | + JANSSEN PHARMA | 4MG/ML | N21224 001 Jun 22, 2001 Jun CAHN |
| >A> | + ORTHO MCNEIL | 4MG/ML | N21224 001 Jun 22, 2001 Jun CAHN |

TABLET; ORAL

RAZADYNE

| | | | | | | |
|-----|------------------|--------------|------------|--------------|-----|------|
| >D> | + JANSSEN PHARMA | EQ 4MG BASE | N21169 001 | Feb 28, 2001 | Jun | CAHN |
| >D> | | EQ 8MG BASE | N21169 002 | Feb 28, 2001 | Jun | CAHN |
| >D> | | EQ 12MG BASE | N21169 003 | Feb 28, 2001 | Jun | CAHN |
| >A> | + ORTHO MCNEIL | EQ 4MG BASE | N21169 001 | Feb 28, 2001 | Jun | CAHN |
| >A> | | EQ 8MG BASE | N21169 002 | Feb 28, 2001 | Jun | CAHN |
| >A> | | EQ 12MG BASE | N21169 003 | Feb 28, 2001 | Jun | CAHN |

GANCICLOVIR SODIUM

INJECTABLE; INJECTION

| | | | | | | |
|-----|--------------------|--------------------|------------|--------------|-----|------|
| >D> | CYTOVENE IV | | | | | |
| >D> | AP + ROCHE PALO | EQ 500MG BASE/VIAL | N19661 001 | Jun 23, 1989 | Jun | DISC |
| >A> | @ | EQ 500MG BASE/VIAL | N19661 001 | Jun 23, 1989 | Jun | DISC |
| | GANCICLOVIR SODIUM | | | | | |
| >D> | AP BEDFORD | EQ 500MG BASE/VIAL | N76222 001 | Jul 16, 2003 | Jun | CRLD |
| >A> | + | EQ 500MG BASE/VIAL | N76222 001 | Jul 16, 2003 | Jun | CRLD |

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLIPIZIDE AND METFORMIN HYDROCHLORIDE

| | | | | | | |
|----|--------|-------------|------------|--------------|-----|------|
| AB | CARACO | 2.5MG;250MG | N77620 001 | Jan 11, 2008 | Jan | NEWA |
| AB | | 2.5MG;500MG | N77620 002 | Jan 11, 2008 | Jan | NEWA |
| AB | | 5MG;500MG | N77620 003 | Jan 11, 2008 | Jan | NEWA |

GLUTAMINE

FOR SOLUTION; ORAL

NUTRESTORE

| | | | | | |
|-----------------------|------------|------------|--------------|-----|------|
| + NUTRITIONAL RESTART | 5GM/PACKET | N21667 001 | Jun 10, 2004 | Mar | CMFD |
|-----------------------|------------|------------|--------------|-----|------|

GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

| | | | | | | |
|----|----------------|-----|------------|--------------|-----|------|
| AA | INDICUS PHARMA | 1MG | N40847 001 | Mar 21, 2008 | Mar | NEWA |
| AA | | 2MG | N40847 002 | Mar 21, 2008 | Mar | NEWA |

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

| | | | | | | |
|-----|-----------------------|-------------------------------------|------------|--------------|-----|------|
| >A> | AP APOTEX CORP | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78198 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78198 002 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP APP PHARMS | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78090 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP BEDFORD LABS | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | N77913 001 | Jun 26, 2008 | Jun | NEWA |
| >A> | AP | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N77186 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N77187 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP DR REDDYS LABS INC | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | N78863 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78880 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP EBEWE PARENTA | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | N78808 001 | Apr 29, 2008 | Apr | NEWA |
| >A> | AP | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78835 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78835 002 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP TEVA PARENTERAL | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N77297 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP WATSON LABS | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78258 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AP | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78258 002 | Jun 30, 2008 | Jun | NEWA |

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

| | | | | |
|---|---------------|--|----------------------------------|----------------------------------|
| AP | WOCKHARDT USA | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | N78566 001 Feb 29, 2008 Feb NEWA | |
| >A> | AP | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78564 001 Jun 30, 2008 Jun NEWA | |
| >A> | AP | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78565 001 Jun 30, 2008 Jun NEWA | |
| GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE | | | | |
| >A> | AP | APP PHARMS | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78096 001 Jun 30, 2008 Jun NEWA |
| >A> | AP | DR REDDYS LABS INC | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78863 002 Jun 30, 2008 Jun NEWA |

SOLUTION; ORAL

GRANISETRON HYDROCHLORIDE

| | | | |
|--------|---------------|------------------|----------------------------------|
| AA | CYPRESS PHARM | EQ 2MG BASE/10ML | N78334 001 Feb 28, 2008 Feb NEWA |
| KYTRIL | | | |
| AA | + ROCHE | EQ 2MG BASE/10ML | N21238 001 Jun 27, 2001 Feb CFTG |

TABLET; ORAL

GRANISETRON HYDROCHLORIDE

| | | | |
|----|-----------------|-------------|----------------------------------|
| AB | APOTEX INC | EQ 1MG BASE | N78843 001 Feb 27, 2008 Feb NEWA |
| AB | CIPLA LTD | EQ 1MG BASE | N78037 001 Feb 27, 2008 Feb NEWA |
| AB | MYLAN | EQ 1MG BASE | N78725 001 Jan 30, 2008 Jan NEWA |
| AB | ORCHID HLTHCARE | EQ 1MG BASE | N78678 001 Feb 13, 2008 Jan NEWA |

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

| | | | |
|----|-------------------|-----------|----------------------------------|
| AB | + ORTHONEUTROGENA | 125MG/5ML | N62483 001 Jan 26, 1984 Feb CAHN |
|----|-------------------|-----------|----------------------------------|

GRISEOFULVIN

| | | | |
|----|----------------------|-----------|----------------------------------|
| AB | PERRIGO CO TENNESSEE | 125MG/5ML | N65200 001 Mar 02, 2005 Apr CAHN |
|----|----------------------|-----------|----------------------------------|

TABLET; ORAL

FULVICIN-U/F

| | | |
|------------|-------|---------------------|
| @ SCHERING | 250MG | N60569 002 Mar DISC |
| @ | 500MG | N60569 001 Mar DISC |

GRIFULVIN V

| | | |
|-------------------|-------|---------------------|
| ORTHONEUTROGENA | 125MG | N62279 001 Feb CAHN |
| + ORTHONEUTROGENA | 250MG | N62279 002 Mar CRLD |
| AB | 250MG | N62279 002 Feb CAHN |
| + ORTHONEUTROGENA | 500MG | N62279 003 Mar CRLD |
| AB | 500MG | N62279 003 Feb CAHN |

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HYDROCHLORIDE

| | | | |
|----|--------------|-------------|----------------------------------|
| AB | AMNEAL PHARM | EQ 1MG BASE | N75109 001 Nov 25, 1998 Feb CAHN |
| AB | | EQ 2MG BASE | N75109 002 Nov 25, 1998 Feb CAHN |

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALDOL

| | | | |
|-----|---------------------------|------------------|----------------------------------|
| >D> | AO + ORTHO MCNEIL | EQ 50MG BASE/ML | N18701 001 Jan 14, 1986 Jun CAHN |
| >D> | AO + ORTHO MCNEIL | EQ 100MG BASE/ML | N18701 002 Jan 31, 1997 Jun CAHN |
| >A> | AO + ORTHO MCNEIL JANSSEN | EQ 50MG BASE/ML | N18701 001 Jan 14, 1986 Jun CAHN |
| >A> | AO + ORTHO MCNEIL JANSSEN | EQ 100MG BASE/ML | N18701 002 Jan 31, 1997 Jun CAHN |

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALDOL

| | | | |
|-----|-------------------|----------------|---------------------|
| >D> | AP + ORTHO MCNEIL | EQ 5MG BASE/ML | N15923 001 Jun CAHN |
|-----|-------------------|----------------|---------------------|

INJECTABLE; INJECTION

HALDOL

>A> AP + ORTHO MCNEIL JANSSEN EQ 5MG BASE/ML N15923 001 Jun CAHN

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM PRESERVATIVE FREE

+ HOSPIRA 2,500 UNITS/ML N05264 014 Apr 07, 1986 Jan CTEC

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

AA HI TECH PHARMA 1.5MG/5ML;5MG/5ML N40613 001 Feb 08, 2008 Jan NEWA
AA MORTON GROVE 1.5MG/5ML;5MG/5ML N88008 001 Mar 03, 1983 Feb CTNAHYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

@ MUTUAL PHARM 10MG N89359 001 Jul 25, 1986 Feb DISC
@ 25MG N89258 001 May 05, 1986 Feb DISC
@ 50MG N89259 001 May 05, 1986 Feb DISCHYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB APOTEX 12.5MG N78389 001 May 16, 2008 May NEWA
AB CADISTA PHARMS 12.5MG N78391 001 Feb 11, 2008 Jan NEWA

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB CARACO 12.5MG N40857 001 May 30, 2008 May NEWA
@ PVT FORM 50MG N86597 001 Apr CAHNHYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERIDE-40/25

AB + AKRIMAX PHARMS 25MG;40MG N18031 001 May CAHN

INDERIDE-80/25

@ AKRIMAX PHARMS 25MG;80MG N18031 002 May CAHN

PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

AB + MYLAN 25MG;80MG N70947 001 Apr 01, 1987 May CRLD

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

LOCOID

>D> AB + TRIAX PHARMS 0.1% N18514 001 Mar 31, 1982 Jun CAHN

>A> AB + TRIAX PHARMS LLC 0.1% N18514 001 Mar 31, 1982 Jun CAHN

LOCOID LIPOCREAM

>D> + TRIAX PHARMS 0.1% N20769 001 Sep 08, 1997 Jun CAHN

>A> + TRIAX PHARMS LLC 0.1% N20769 001 Sep 08, 1997 Jun CAHN

LOTION; TOPICAL

LOCOID

>D> + TRIAX PHARMS 0.1% N22076 001 May 18, 2007 Jun CAHN

>A> + TRIAX PHARMS LLC 0.1% N22076 001 May 18, 2007 Jun CAHN

OINTMENT; TOPICAL

LOCOID

>D> AB + TRIAX PHARMS 0.1% N18652 001 Oct 29, 1982 Jun CAHN

OINTMENT; TOPICAL

LOCOID

>A> AB + TRIAX PHARMS LLC 0.1% N18652 001 Oct 29, 1982 Jun CAHN

SOLUTION; TOPICAL

LOCOID

>D> AT + TRIAX PHARMS 0.1% N19116 001 Feb 25, 1987 Jun CAHN

>A> AT + TRIAX PHARMS LLC 0.1% N19116 001 Feb 25, 1987 Jun CAHN

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

CORTISPORIN

@ MONARCH PHARMS 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML N50169 001 May DISC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

+ ALCON UNIVERSAL 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML N62874 001 May 11, 1988 May CRLD

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

DILAUDID-HP

>D> AP + ABBOTT 10MG/ML N19034 001 Jan 11, 1984 Jun CAHN

>D> + 250MG/VIAL N19034 002 Aug 04, 1994 Jun CAHN

>A> AP + PURDUE PHARM PRODS 10MG/ML N19034 001 Jan 11, 1984 Jun CAHN

>A> + 250MG/VIAL N19034 002 Aug 04, 1994 Jun CAHN

HYDROMORPHONE HYDROCHLORIDE

>A> AP HOSPIRA INC 10MG/ML N78591 001 Jun 17, 2008 Jun NEWA

SOLUTION; ORAL

DILAUDID

>D> AA + ABBOTT 5MG/5ML N19891 001 Dec 07, 1992 Jun CAHN

>A> AA + PURDUE PHARM PRODS 5MG/5ML N19891 001 Dec 07, 1992 Jun CAHN

TABLET; ORAL

DILAUDID

>D> AB ABBOTT 2MG N19892 003 Nov 09, 2007 Jun CAHN

>D> AB + 4MG N19892 002 Nov 09, 2007 Jun CAHN

>D> AB + 8MG N19892 001 Dec 07, 1992 Jun CAHN

>A> AB PURDUE PHARM PRODS 2MG N19892 003 Nov 09, 2007 Jun CAHN

>A> AB + 4MG N19892 002 Nov 09, 2007 Jun CAHN

>A> AB + 8MG N19892 001 Dec 07, 1992 Jun CAHN

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

AB IPCA LABS LTD 200MG N40766 001 Jun 14, 2007 Jan CMFD

HYDROXYUREA

TABLET; ORAL

HYDROXYUREA

@ BARR 1GM N75734 001 Aug 29, 2000 Jan DISC

HYDROXYZINE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

AB INVAGEN PHARMS 10MG N40812 001 Mar 12, 2008 Feb NEWA

AB + 25MG N40812 002 Mar 12, 2008 Feb NEWA

AB + 50MG N40812 003 Mar 12, 2008 Feb NEWA

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

| | | | | | | | |
|-----|----|--------------------|------|------------|--------------|-----|------|
| >A> | AB | ANDAPHARM | 10MG | N40804 001 | Jun 30, 2008 | Jun | NEWA |
| >A> | AB | | 25MG | N40804 002 | Jun 30, 2008 | Jun | NEWA |
| >A> | AB | | 50MG | N40804 003 | Jun 30, 2008 | Jun | NEWA |
| | AB | HETERO DRUGS LTD | 10MG | N40805 001 | May 29, 2008 | May | NEWA |
| | AB | | 25MG | N40805 002 | May 29, 2008 | May | NEWA |
| | AB | | 50MG | N40805 003 | May 29, 2008 | May | NEWA |
| | AB | INVAGEN PHARMS | 10MG | N40812 001 | Mar 12, 2008 | Mar | CAIN |
| | AB | | 25MG | N40812 002 | Mar 12, 2008 | Mar | CAIN |
| | AB | | 50MG | N40812 003 | Mar 12, 2008 | Mar | CAIN |
| | AB | NORTHSTAR HLTHCARE | 10MG | N40841 001 | Mar 31, 2008 | Mar | NEWA |
| | AB | | 25MG | N40842 001 | Mar 31, 2008 | Mar | NEWA |
| | AB | | 50MG | N40840 001 | Mar 31, 2008 | Mar | NEWA |
| | AB | SUN PHARM INDS INC | 10MG | N40899 001 | Jun 10, 2008 | May | NEWA |
| | AB | | 25MG | N40899 002 | Jun 10, 2008 | May | NEWA |
| | AB | | 50MG | N40899 003 | Jun 10, 2008 | May | NEWA |

IBUPROFEN

TABLET; ORAL

IBUPROFEN

@ LEINER

300MG

N71266 001 Oct 15, 1986 Apr DISC

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HYDROCHLORIDE

| | | | | | | |
|----|----------------|------|------------|--------------|-----|------|
| AB | ACTAVIS TOTOWA | 10MG | N40753 001 | Feb 28, 2008 | Feb | NEWA |
| AB | | 25MG | N40752 001 | Feb 28, 2008 | Feb | NEWA |
| AB | | 50MG | N40751 001 | Feb 28, 2008 | Feb | NEWA |

IMIPRAMINE PAMOATE

CAPSULE; ORAL

TOFRANIL-PM

+ TYCO HLTHCARE

EQ 75MG HCL

N17090 001

Jan CRLD

EQ 150MG HCL

N17090 002

Jan CRLD

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE

| | | | | | | |
|----|---------------------|--------|------------|--------------|-----|------|
| AB | + MYLAN | 2.5MG | N74461 001 | Mar 27, 1996 | Mar | CRLD |
| | LOZOL | | | | | |
| | @ SANOFI AVENTIS US | 1.25MG | N18538 002 | Apr 29, 1993 | Mar | DISC |
| | @ | 2.5MG | N18538 001 | Jul 06, 1983 | Mar | DISC |

INDOMETHACIN

CAPSULE; ORAL

INDOCIN

@ IROKO PHARMS

25MG

N16059 001

Feb CAHN

@

50MG

N16059 002

Feb CAHN

INDOMETHACIN

| | | | | | | |
|----|-------------|------|------------|--------------|-----|------|
| AB | IVAX PHARMS | 25MG | N70719 001 | Feb 12, 1986 | Jan | CMFD |
| AB | | 50MG | N70756 001 | Feb 12, 1986 | Jan | CMFD |

CAPSULE, EXTENDED RELEASE; ORAL

| | | |
|--|------|----------------------------------|
| INDOCIN SR @ IROKO PHARMS | 75MG | N18185 001 Feb 23, 1982 Feb CAHN |
| SUPPOSITORY; RECTAL INDOCIN @ IROKO PHARMS | 50MG | N17814 001 Aug 13, 1984 Feb CAHN |

INDOMETHACIN SODIUMINJECTABLE; INJECTION
INDOCIN I.V.

| | | |
|-------------------------|------------------|----------------------------------|
| >D> + OVATION PHARMS | EQ 1MG BASE/VIAL | N18878 001 Jan 30, 1985 Jun CFTG |
| >A> AP + | EQ 1MG BASE/VIAL | N18878 001 Jan 30, 1985 Jun CFTG |
| >A> INDOMETHACIN SODIUM | | |
| >A> AP BEDFORD | EQ 1MG BASE/VIAL | N78713 001 Jul 16, 2008 Jun NEWA |

IOTHALAMATE SODIUM, I-125INJECTABLE; INJECTION
GLOFIL-125
@ ISOTEX

| | | |
|---------------|------------|----------|
| 250-300uCi/ML | N17279 001 | May DISC |
|---------------|------------|----------|

IRINOTECAN HYDROCHLORIDEINJECTABLE; INJECTION
CAMPTOSAR

| | | |
|-----------------|---------------------|----------------------------------|
| AP + PFIZER INC | 40MG/2ML (20MG/ML) | N20571 001 Jun 14, 1996 Feb CFTG |
| AP + | 100MG/5ML (20MG/ML) | N20571 002 Jun 14, 1996 Feb CFTG |

IRINOTECAN HYDROCHLORIDE

| | | |
|-----------------------|----------------------|----------------------------------|
| AP ACTAVIS TOTOWA | 40MG/2ML (20MG/ML) | N78589 001 Feb 27, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N78589 002 Feb 27, 2008 Feb NEWA |
| AP APP PHARMS | 40MG/2ML (20MG/ML) | N77776 001 Feb 27, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N77776 002 Feb 27, 2008 Feb NEWA |
| AP DABUR ONCOLOGY PLC | 40MG/2ML (20MG/ML) | N78188 001 Feb 27, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N78188 002 Feb 27, 2008 Feb NEWA |
| AP HOSPIRA | 40MG/2ML (20MG/ML) | N77915 001 Feb 27, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N77915 002 Feb 27, 2008 Feb NEWA |
| + | 500MG/25ML (20MG/ML) | N78796 001 Feb 27, 2008 Feb NEWA |
| AP SANDOZ | 40MG/2ML (20MG/ML) | N77994 001 Feb 27, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N77994 002 Feb 27, 2008 Feb NEWA |
| AP SUN PHARMA GLOBAL | 40MG/2ML (20MG/ML) | N78805 001 Apr 21, 2008 Apr NEWA |
| AP | 100MG/5ML (20MG/ML) | N78805 002 Apr 21, 2008 Apr NEWA |
| AP TEVA PARENTERAL | 40MG/2ML (20MG/ML) | N77260 001 Feb 27, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N77260 002 Feb 27, 2008 Feb NEWA |
| AP WATSON LABS | 40MG/2ML (20MG/ML) | N77219 001 Feb 20, 2008 Feb NEWA |
| AP | 100MG/5ML (20MG/ML) | N77219 002 Feb 20, 2008 Feb NEWA |

ISONIAZIDTABLET; ORAL
ISONIAZID
@ MUTUAL PHARM

| | | |
|-------|------------|----------|
| 300MG | N83633 001 | Mar DISC |
|-------|------------|----------|

ISOPROTERENOL HYDROCHLORIDEINJECTABLE; INJECTION
ISOPROTERENOL HYDROCHLORIDE
@ HOSPIRA

| | | |
|-----------|------------|----------|
| 0.02MG/ML | N83283 001 | Apr DISC |
|-----------|------------|----------|

ISOSORBIDE DINITRATE

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

| | | | | |
|--------------------------------|---|-------------|------|----------------------------------|
| AB | + | WATSON LABS | 5MG | N86031 001 Sep 29, 1987 Jan CRLD |
| TABLET, EXTENDED RELEASE; ORAL | | | | |
| ISOSORBIDE DINITRATE | | | | |
| AB | | COREPHARMA | 40MG | N40723 001 Mar 17, 2008 Mar NEWA |
| AB | + | INWOOD LABS | 40MG | N40009 001 Dec 30, 1998 Mar CTEC |

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
IMDUR

| | | | | |
|------------------------|-------|----------------------------------|-------|----------------------------------|
| @ SCHERING PLOUGH | 30MG | N20225 001 Aug 12, 1993 May DISC | | |
| @ | 60MG | N20225 002 Aug 12, 1993 May DISC | | |
| @ | 120MG | N20225 003 Mar 30, 1995 May DISC | | |
| ISOSORBIDE MONONITRATE | | | | |
| AB | + | KREMERS URBAN | 120MG | N75155 003 Aug 04, 2000 May CRLD |

ITRACONAZOLE

CAPSULE; ORAL
SPORANOX

| | | | | | |
|-----------------------|----|---|----------------|---------|----------------------------------|
| >D> | AB | + | JANSSEN PHARMA | 100MG | N20083 001 Sep 11, 1992 Jun CAHN |
| >A> | AB | + | ORTHO MCNEIL | 100MG | N20083 001 Sep 11, 1992 Jun CAHN |
| INJECTABLE; INJECTION | | | | | |
| SPORANOX | | | | | |
| >D> | | + | JANSSEN PHARMA | 10MG/ML | N20966 001 Mar 30, 1999 Jun CAHN |
| >A> | | + | ORTHO MCNEIL | 10MG/ML | N20966 001 Mar 30, 1999 Jun CAHN |
| SOLUTION; ORAL | | | | | |
| SPORANOX | | | | | |
| >D> | | + | JANSSEN PHARMA | 10MG/ML | N20657 001 Feb 21, 1997 Jun CAHN |
| >A> | | + | ORTHO MCNEIL | 10MG/ML | N20657 001 Feb 21, 1997 Jun CAHN |

KETOCONAZOLE

TABLET; ORAL
NIZORAL

| | | | | | |
|-----|----|---|----------------|-------|---------------------|
| >D> | AB | + | JANSSEN PHARMA | 200MG | N18533 001 Jun CAHN |
| >A> | AB | + | ORTHO MCNEIL | 200MG | N18533 001 Jun CAHN |

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

| | | | | |
|----|--|----------|---------|----------------------------------|
| AP | | LUITPOLD | 15MG/ML | N78145 001 Jan 14, 2008 Jan NEWA |
| AP | | | 30MG/ML | N78145 002 Jan 14, 2008 Jan NEWA |

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION
VIADUR

| | | | | |
|-----------------------|--------------|----------------------------------|-----------|----------------------------------|
| + JOHNSON AND JOHNSON | EQ 65MG BASE | N21088 001 Mar 03, 2000 Feb CAHN | | |
| INJECTABLE; INJECTION | | | | |
| LUPRON | | | | |
| AP | + | ABBOTT ENDO | 1MG/0.2ML | N19010 001 Apr 09, 1985 Apr CAHN |
| LUPRON DEPOT | | | | |
| + ABBOTT ENDO | 3.75MG/VIAL | N20011 001 Oct 22, 1990 Apr CAHN | | |
| + | 7.5MG/VIAL | N19732 001 Jan 26, 1989 Apr CAHN | | |
| + | 22.5MG/VIAL | N20517 001 Dec 22, 1995 Apr CAHN | | |

INJECTABLE; INJECTION

| | | | | | | |
|------------------|-------------------------|--|--------|-----|--------------|----------|
| LUPRON DEPOT-3 | | | | | | |
| + ABBOTT ENDO | 11.25MG/VIAL | | N20708 | 001 | Mar 07, 1997 | Apr CAHN |
| LUPRON DEPOT-4 | | | | | | |
| + ABBOTT ENDO | 30MG/VIAL | | N20517 | 002 | May 30, 1997 | Apr CAHN |
| LUPRON DEPOT-PED | | | | | | |
| @ ABBOTT ENDO | 3.75MG/VIAL, 7.5MG/VIAL | | N20263 | 003 | Apr 16, 1993 | Apr CAHN |
| @ | 7.5MG/VIAL, 7.5MG/VIAL | | N20263 | 004 | Apr 16, 1993 | Apr CAHN |
| + @ | 7.5MG/VIAL | | N20263 | 002 | Apr 16, 1993 | Apr CAHN |
| @ | 3.75MG/VIAL, 7.5MG/VIAL | | N20263 | 003 | Apr 16, 1993 | Apr CAHN |
| + @ | 11.25MG/VIAL | | N20263 | 005 | Jan 21, 1994 | Apr CAHN |
| + @ | 15MG/VIAL | | N20263 | 006 | Jan 21, 1994 | Apr CAHN |

LEVALBUTEROL HYDROCHLORIDESOLUTION; INHALATION

LEVALBUTEROL HYDROCHLORIDE

| | | | | | | |
|---------------|-----------------|--------|-----|--------------|-----|------|
| AN BREATH LTD | EQ 0.0103% BASE | N77756 | 003 | Apr 09, 2008 | Mar | NEWA |
| AN | EQ 0.021% BASE | N77756 | 001 | Apr 09, 2008 | Mar | NEWA |
| AN | EQ 0.042% BASE | N77756 | 002 | Apr 09, 2008 | Mar | NEWA |
| XOPENEX | | | | | | |
| AN + SEPRACOR | EQ 0.0103% BASE | N20837 | 003 | Jan 30, 2002 | Mar | CFTG |
| AN + | EQ 0.021% BASE | N20837 | 001 | Mar 25, 1999 | Mar | CFTG |
| AN + | EQ 0.042% BASE | N20837 | 002 | Mar 25, 1999 | Mar | CFTG |

LEVO CETIRIZINE DIHYDROCHLORIDESOLUTION; ORAL

XYZAL

| | | | | | | |
|-----------|-----------|--------|-----|--------------|-----|------|
| + UCB INC | 2.5MG/5ML | N22157 | 001 | Jan 28, 2008 | Jan | NEWA |
|-----------|-----------|--------|-----|--------------|-----|------|

LEVOFLOXACININJECTABLE; INJECTION

LEVAQUIN

| | | | | | | |
|--|-------------------------|--------|-----|--------------|-----|------|
| >A+ ORTHO MCNEIL | EQ 500MG /20ML(25MG/ML) | N20635 | 001 | Dec 20, 1996 | Jun | CAHN |
| >A+ + | EQ 750MG /30ML(25MG/ML) | N20635 | 004 | Dec 20, 1996 | Jun | CAHN |
| >D+ + ORTHO MCNEIL PHARM | EQ 500MG /20ML(25MG/ML) | N20635 | 001 | Dec 20, 1996 | Jun | CAHN |
| >D+ + | EQ 750MG /30ML(25MG/ML) | N20635 | 004 | Dec 20, 1996 | Jun | CAHN |
| LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | |
| >A+ + ORTHO MCNEIL | EQ 250MG /50ML(5MG/ML) | N20635 | 002 | Dec 20, 1996 | Jun | CAHN |
| >A+ + | EQ 500MG /100ML(5MG/ML) | N20635 | 003 | Dec 20, 1996 | Jun | CAHN |
| >A+ + | EQ 750MG /150ML(5MG/ML) | N20635 | 005 | Dec 20, 1996 | Jun | CAHN |
| >D+ + ORTHO MCNEIL PHARM | EQ 250MG /50ML(5MG/ML) | N20635 | 002 | Dec 20, 1996 | Jun | CAHN |
| >D+ + | EQ 500MG /100ML(5MG/ML) | N20635 | 003 | Dec 20, 1996 | Jun | CAHN |
| >D+ + | EQ 750MG /150ML(5MG/ML) | N20635 | 005 | Dec 20, 1996 | Jun | CAHN |

SOLUTION; ORAL

LEVAQUIN

| | | | | | | |
|--------------------------|------------|--------|-----|--------------|-----|------|
| >A+ + ORTHO MCNEIL | 250MG/10ML | N21721 | 001 | Oct 21, 2004 | Jun | CAHN |
| >D+ + ORTHO MCNEIL PHARM | 250MG/10ML | N21721 | 001 | Oct 21, 2004 | Jun | CAHN |

TABLET; ORAL

LEVAQUIN

| | | | | | | |
|------------------------|-------|--------|-----|--------------|-----|------|
| >A+ ORTHO MCNEIL | 250MG | N20634 | 001 | Dec 20, 1996 | Jun | CAHN |
| >A+ + | 500MG | N20634 | 002 | Dec 20, 1996 | Jun | CAHN |
| >A+ + | 750MG | N20634 | 003 | Sep 08, 2000 | Jun | CAHN |
| >D+ ORTHO MCNEIL PHARM | 250MG | N20634 | 001 | Dec 20, 1996 | Jun | CAHN |
| >D+ + | 500MG | N20634 | 002 | Dec 20, 1996 | Jun | CAHN |
| >D+ + | 750MG | N20634 | 003 | Sep 08, 2000 | Jun | CAHN |

LEVOLEUCOVORIN CALCIUM

POWDER; IV (INFUSION)
 LEVOLEUCOVORIN
 + SPECTRUM PHARMS EQ 50MG BASE/VIAL N20140 001 Mar 07, 2008 Mar NEWA

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
 POLOCAINE W/ LEVONORDEFRIN
 AP + DENTSPLY PHARM 0.05MG/ML; 2% N89517 001 Apr 14, 1988 Jan CRLD

LEVOTHYROXINE SODIUM**

**Refer to Annual Edition Preface Section 1.8 Levothyroxine Sodium for amplifying information

| | | | | | |
|--------------------|---------|--|--|--|----------------------------------|
| TABLET; ORAL | | | | | |
| LEVOXYL | | | | | |
| AB1, + KING PHARMS | 0.2MG | | | | N21301 011 May 25, 2001 Jan CRLD |
| AB3 @ | 0.3MG | | | | N21301 012 May 25, 2001 Jan DISC |
| UNITHROID | | | | | |
| AB1, STEVENS J | 0.137MG | | | | N21210 012 Feb 08, 2008 Feb NEWA |
| AB2, | | | | | |
| AB3 | | | | | |

LIDOCAINE HYDROCHLORIDE

| | | | | | | |
|-----------------------------|-----|--|--|--|----------------------------------|----------|
| INJECTABLE; INJECTION | | | | | | |
| XYLOCAINE PRESERVATIVE FREE | | | | | | |
| AP APP PHARMS | 1% | | | | N16801 005 Jan 19, 1988 Apr CAHN | |
| AP + | 2% | | | | N16801 001 | Apr CAHN |
| AP | 4% | | | | N16801 002 | Apr CAHN |
| AP + | 10% | | | | N16801 003 | Apr CAHN |
| AP + | 20% | | | | N16801 004 | Apr CAHN |

>D> LIDOCAINE HYDROCHLORIDE; OXYTETRACYCLINE

| | | | | | | |
|---------------------------|-------------|--|--|--|------------|----------|
| >D> INJECTABLE; INJECTION | | | | | | |
| >D> TERRAMYCIN | | | | | | |
| >D> + PFIZER | 2%;50MG/ML | | | | N60567 001 | Jun DISC |
| >A> @ | 2%;50MG/ML | | | | N60567 001 | Jun DISC |
| >D> + | 2%;125MG/ML | | | | N60567 002 | Jun DISC |
| >A> @ | 2%;125MG/ML | | | | N60567 002 | Jun DISC |

LINDANE

| | | | | | | |
|------------------|----|--|--|--|------------|----------|
| LOTION; TOPICAL | | | | | | |
| LINDANE | | | | | | |
| @ AL AND S | 1% | | | | N87313 001 | May CAHN |
| SHAMPOO; TOPICAL | | | | | | |
| LINDANE | | | | | | |
| AT + AL AND S | 1% | | | | N87266 001 | May CAHN |

LITHIUM CARBONATE

| | | | | | | |
|-------------------|-------|--|--|--|----------------------------------|----------|
| CAPSULE; ORAL | | | | | | |
| ESCALITH | | | | | | |
| AB NOVEN THERAP | 300MG | | | | N16860 001 | Jan CAHN |
| LITHIUM CARBONATE | | | | | | |
| AB + ROXANE | 600MG | | | | N17812 003 Jan 28, 1987 Mar CTEC | |
| AB WEST WARD | 600MG | | | | N78763 001 Apr 15, 2008 Mar NEWA | |

TABLET, EXTENDED RELEASE; ORAL
LITHIUM CARBONATE

| | | | | |
|-----|----|--------------|-------|----------------------------------|
| >D> | AB | BARR | 300MG | N76170 001 Jun 10, 2002 Jun CTEC |
| >A> | BX | | 300MG | N76170 001 Jun 10, 2002 Jun CTEC |
| | | LITHOBID | | |
| AB | + | NOVEN THERAP | 300MG | N18027 001 Jan CAHN |

LOMEFLOXACIN HYDROCHLORIDE

| | | | | |
|-----|---|--------------|---------------|----------------------------------|
| >D> | | TABLET; ORAL | | |
| >D> | | MAXAQWIN | | |
| >D> | + | PHARMACIA | EQ 400MG BASE | N20013 001 Feb 21, 1992 Jun DISC |
| >A> | @ | | EQ 400MG BASE | N20013 001 Feb 21, 1992 Jun DISC |

LOVASTATIN

| | | | | |
|----|--|--------------|------|----------------------------------|
| | | TABLET; ORAL | | |
| | | LOVASTATIN | | |
| AB | | LUPIN | 10MG | N78296 001 Mar 14, 2008 Mar NEWA |

LOXPINE SUCCINATE

| | | | | |
|-----|----|---------------|--------------|---------------------|
| | | CAPSULE; ORAL | | |
| >D> | | LOXITANE | | |
| >D> | AB | WATSON LABS | EQ 5MG BASE | N17525 001 Jun DISC |
| >A> | | @ | EQ 5MG BASE | N17525 001 Jun DISC |
| >D> | AB | | EQ 10MG BASE | N17525 002 Jun DISC |
| >A> | | @ | EQ 10MG BASE | N17525 002 Jun DISC |
| >D> | AB | + | EQ 25MG BASE | N17525 003 Jun DISC |
| >A> | | @ | EQ 25MG BASE | N17525 003 Jun DISC |
| >D> | AB | | EQ 50MG BASE | N17525 004 Jun DISC |
| >A> | | @ | EQ 50MG BASE | N17525 004 Jun DISC |

LUBIPROSTONE

| | | | | |
|--|--|----------------|------|----------------------------------|
| | | CAPSULE; ORAL | | |
| | | AMITIZA | | |
| | | SUCAMPO PHARMS | 8UGM | N21908 002 Apr 29, 2008 Apr NEWA |

MELOXICAM

| | | | | |
|--|--|--------------|-------|----------------------------------|
| | | TABLET; ORAL | | |
| | | MELOXICAM | | |
| | | @ ROXANE | 7.5MG | N77925 001 Jul 19, 2006 Feb DISC |
| | | @ | 15MG | N77925 002 Jul 19, 2006 Feb DISC |

MEPIVACAINE HYDROCHLORIDE

| | | | | |
|----|--|---------------------------|----|----------------------------------|
| | | INJECTABLE; INJECTION | | |
| | | MEPIVACAINE HYDROCHLORIDE | | |
| AP | | HOSPIRA INC | 3% | N40806 001 Apr 28, 2008 Apr NEWA |

MEPROBAMATE

| | | | | |
|----|---|----------------|-------|----------------------------------|
| | | TABLET; ORAL | | |
| | | MEPROBAMATE | | |
| AA | | INVAGEN PHARMS | 200MG | N40797 001 Feb 27, 2008 Feb NEWA |
| AA | | | 400MG | N40797 002 Feb 27, 2008 Feb NEWA |
| | | @ PVT FORM | 400MG | N14601 001 Apr CAHN |
| AA | + | WATSON LABS | 400MG | N83308 001 Feb CTEC |

MESALAMINE

ENEMA; RECTAL
 >D> ROWASA
 >D> AB + ALAVEN PHARM 4GM/60ML N19618 001 Dec 24, 1987 Jun CTNA
 >A> SFROWASA
 >A> AB + ALAVEN PHARM 4GM/60ML N19618 001 Dec 24, 1987 Jun CTNA
 TABLET, DELAYED RELEASE; ORAL
 MESALAMINE
 + PROCTOR AND GAMBLE 800MG N21830 001 May 29, 2008 May NEWA

MESTRANOL; NORETHINDRONE

TABLET; ORAL-28
 ORTHO-NOVUM 1/50 28
 >A> AB ORTHO MCNEIL 0.05MG;1MG N16709 001 Jun CAHN
 >D> AB ORTHO MCNEIL PHARM 0.05MG;1MG N16709 001 Jun CAHN

METAPROTERENOL SULFATE

SYRUP; ORAL
 METAPROTERENOL SULFATE
 @ MORTON GROVE 10MG/5ML N74702 001 Mar 24, 1997 Feb DISC
 AA + SILARK 10MG/5ML N73632 001 Jul 22, 1992 Feb CRLD

METFORMIN HYDROCHLORIDE

TABLET; ORAL
 METFORMIN HYDROCHLORIDE
 AB GLENMARK GENERICS 500MG N78170 001 May 23, 2008 May NEWA
 AB 850MG N78170 002 May 23, 2008 May NEWA
 AB 1GM N78170 003 May 23, 2008 May NEWA
 TABLET, EXTENDED RELEASE; ORAL
 METFORMIN HYDROCHLORIDE
 AB NEUROSCI INC 500MG N78321 001 Apr 17, 2008 Mar NEWA
 AB 750MG N78321 002 Apr 17, 2008 Mar NEWA

>A> METFORMIN HYDROCHLORIDE; REPAGLINIDE

>A> TABLET; ORAL
 >A> PRANDIMET
 >A> NOVO NORDISK INC 500MG;1MG N22386 001 Jun 23, 2008 Jun NEWA
 >A> + 500MG;2MG N22386 002 Jun 23, 2008 Jun NEWA

METHSCOPOLAMINE BROMIDE

TABLET; ORAL
 METHSCOPOLAMINE BROMIDE
 @ PVT FORM 2.5MG N80970 001 Apr CAHN
 PAMINE
 AA + NYCOMED US 2.5MG N08848 001 Feb CAHN
 PAMINE FORTE
 AA + NYCOMED US 5MG N08848 002 Mar 25, 2003 Feb CAHN

METHYLNALTREXONE BROMIDE

SOLUTION; SUBCUTANEOUS
 RELISTOR
 + PROGENICS 12MG/0.6ML (12MG/0.6ML) N21964 001 Apr 24, 2008 Apr NEWA

METHYLPHENIDATE

FILM, EXTENDED RELEASE; TRANSDERMAL

DAYTRANA

SHIRE

10MG/9HR (1.1MG/HR)
15MG/9HR (1.6MG/HR)
20MG/9HR (2.2MG/HR)N21514 001 Apr 06, 2006 Apr CRLD
N21514 002 Apr 06, 2006 Apr CRLD
N21514 003 Apr 06, 2006 Apr CRLDMETHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CONCERTA

| | | | |
|-----|----------------------|------|----------------------------------|
| >D> | ALZA | 18MG | N21121 001 Aug 01, 2000 Jun CAHN |
| >D> | | 27MG | N21121 004 Apr 01, 2002 Jun CAHN |
| >D> | | 36MG | N21121 002 Aug 01, 2000 Jun CAHN |
| >D> | + | 54MG | N21121 003 Dec 08, 2000 Jun CAHN |
| >A> | ORTHO MCNEIL JANSSEN | 18MG | N21121 001 Aug 01, 2000 Jun CAHN |
| >A> | | 27MG | N21121 004 Apr 01, 2002 Jun CAHN |
| >A> | | 36MG | N21121 002 Aug 01, 2000 Jun CAHN |
| >A> | + | 54MG | N21121 003 Dec 08, 2000 Jun CAHN |

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

METHYLTTESTOSTERONE

@ PVT FORM

5MG

N83836 001 Apr CAHN

TABLET; ORAL

METHYLTTESTOSTERONE

@ PVT FORM

5MG

N80214 001 Apr CAHN

@

10MG

N80214 002 Apr CAHN

@

25MG

N80214 003 Apr CAHN

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

| | | | | | |
|-----|----|----------------------|-----------------|----------------------------------|----------------------------------|
| >D> | AA | ACTAVIS MID ATLANTIC | EQ 5MG BASE/5ML | N71340 001 Aug 18, 1988 Jun DISC | |
| >A> | | @ | EQ 5MG BASE/5ML | N71340 001 Aug 18, 1988 Jun DISC | |
| | AA | + | MORTON GROVE | EQ 5MG BASE/5ML | N74703 001 Oct 31, 1997 Feb CAHN |

TABLET; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

| | | | | |
|-----|----|---------------|--------------|----------------------------------|
| >A> | AB | IPCA LABS LTD | EQ 5MG BASE | N78807 001 Jun 12, 2008 Jun NEWA |
| >A> | AB | | EQ 10MG BASE | N78807 002 Jun 12, 2008 Jun NEWA |

REGLAN

| | | | |
|----|--------------|--------------|----------------------------------|
| AB | ALAVEN PHARM | EQ 5MG BASE | N17854 002 May 05, 1987 Mar CAHN |
| AB | + | EQ 10MG BASE | N17854 001 Mar CAHN |

TABLET, ORALLY DISINTEGRATING; ORAL

REGLAN ODT

| | | | | |
|-----|--|----------------|--------------|----------------------------------|
| >D> | | @ ALAVEN PHARM | EQ 5MG BASE | N21793 001 Jun 10, 2005 Jun CMFD |
| >A> | | | EQ 5MG BASE | N21793 001 Jun 10, 2005 Jun CMFD |
| | | @ | EQ 5MG BASE | N21793 001 Jun 10, 2005 Mar CAHN |
| >D> | | @ | EQ 10MG BASE | N21793 002 Jun 10, 2005 Jun CMFD |
| >A> | | + | EQ 10MG BASE | N21793 002 Jun 10, 2005 Jun CMFD |
| | | @ | EQ 10MG BASE | N21793 002 Jun 10, 2005 Mar CAHN |

METOLAZONE

TABLET; ORAL

METOLAZONE

@ WATSON LABS

10MG

N76891 001 Jul 21, 2004 May DISC

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

METOPROLOL SUCCINATE

| | | | | | | |
|----|----------|-------------------|------------|--------------|-----|------|
| AB | KV PHARM | EQ 25MG TARTRATE | N77779 001 | Mar 20, 2008 | Mar | NEWA |
| AB | | EQ 50MG TARTRATE | N77176 001 | May 14, 2008 | May | NEWA |
| AB | SANDOZ | EQ 100MG TARTRATE | N76969 003 | Mar 20, 2008 | Mar | NEWA |
| AB | | EQ 200MG TARTRATE | N76969 004 | Mar 20, 2008 | Mar | NEWA |

METOPROLOL TARTRATE

INJECTABLE; INJECTION

METOPROLOL TARTRATE

| | | | | | | |
|-----|---------------------|--------|------------|--------------|-----|------|
| AP | HOSPIRA | 1MG/ML | N78085 001 | Apr 29, 2008 | Apr | NEWA |
| | TABLET; ORAL | | | | | |
| | METOPROLOL TARTRATE | | | | | |
| >A> | AB OHM LABS | 25MG | N78459 001 | Jun 17, 2008 | Jun | NEWA |
| >A> | AB | 50MG | N78459 002 | Jun 17, 2008 | Jun | NEWA |
| >A> | AB | 100MG | N78459 003 | Jun 17, 2008 | Jun | NEWA |

METRONIDAZOLE

INJECTABLE; INJECTION

METRONIDAZOLE IN PLASTIC CONTAINER

| | | | | | | |
|----|---------------------|-------------|------------|--------------|-----|------|
| AP | CLARIS LIFESCIENCES | 500MG/100ML | N78084 001 | Mar 31, 2008 | Mar | NEWA |
|----|---------------------|-------------|------------|--------------|-----|------|

MICONAZOLE NITRATE

CREAM; TOPICAL

MONISTAT-DERM

| | | | | | |
|---|-----------------|----|------------|-----|------|
| + | ORTHONEUTROGENA | 2% | N17494 001 | Feb | CAHN |
|---|-----------------|----|------------|-----|------|

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HYDROCHLORIDE

| | | | | | | |
|-----|--------------|----------------|------------|--------------|-----|------|
| >D> | AP HOSPIRA | EQ 1MG BASE/ML | N75396 001 | Jun 20, 2000 | Jun | DISC |
| >A> | @ | EQ 1MG BASE/ML | N75396 001 | Jun 20, 2000 | Jun | DISC |
| | AP WOCKHARDT | EQ 1MG BASE/ML | N78141 001 | May 30, 2008 | May | NEWA |
| | AP | EQ 5MG BASE/ML | N78141 002 | May 30, 2008 | May | NEWA |

MILRINONE LACTATE

INJECTABLE; INJECTION

MILRINONE LACTATE IN 5% DEXTROSE IN PLASTIC CONTAINER

| | | | | | | |
|-----|---------------|---------------------------------------|------------|--------------|-----|------|
| >D> | AP APOTEX INC | EQ 20MG BASE/100ML | N77151 001 | Jul 20, 2005 | Jun | CPOT |
| >A> | AP | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N77151 001 | Jul 20, 2005 | Jun | CPOT |

MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | | | |
|-----|------------|---------------------------------------|------------|--------------|-----|------|
| >D> | AP B BRAUN | EQ 20MG BASE/100ML | N76414 001 | Aug 18, 2004 | Jun | CPOT |
| >A> | AP | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N76414 001 | Aug 18, 2004 | Jun | CPOT |

| | | | | | | |
|-----|--------------------|---------------------------------------|------------|--------------|-----|------|
| >D> | AP BAXTER HLTHCARE | EQ 20MG BASE/100ML | N75510 001 | May 28, 2002 | Jun | CPOT |
| >A> | AP | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N75510 001 | May 28, 2002 | Jun | CPOT |

| | | | | | | |
|-----|----|---------------------------------------|------------|--------------|-----|------|
| >D> | AP | EQ 20MG BASE/100ML | N75834 001 | May 28, 2002 | Jun | CPOT |
| >A> | AP | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N75834 001 | May 28, 2002 | Jun | CPOT |

| | | | | | | |
|-----|--------------|---------------------------------------|------------|--------------|-----|------|
| >A> | AP | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N76259 001 | Aug 08, 2002 | Jun | CPOT |
| | BEDFORD LABS | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N78113 001 | May 21, 2008 | May | NEWA |

| | | | | | | |
|--|----|---------------------------------------|------------|--------------|-----|------|
| | AP | EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML) | N78113 002 | May 21, 2008 | May | NEWA |
|--|----|---------------------------------------|------------|--------------|-----|------|

INJECTABLE; INJECTION

MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|--|--|--------|--------------|--------------|------|------|
| >D> | AP | HOSPIRA | EQ 20MG BASE/100ML | N75885 | 001 | May 28, 2002 | Jun | CPOT |
| >A> | AP | | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N75885 | 001 | May 28, 2002 | Jun | CPOT |
| | | MILRINONE LACTOSE IN 5% DEXTROSE | | | | | | |
| >D> | AP | BAXTER HLTHCARE | EQ 20MG BASE/100ML | N76259 | 001 | Aug 08, 2002 | Jun | CPOT |
| | | PRIMACOR | | | | | | |
| | | @ SANOFI AVENTIS US | EQ 1MG BASE/ML | N19436 | 001 | Dec 31, 1987 | May | DISC |
| | | PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | |
| >D> | AP | + SANOFI AVENTIS US | EQ 20MG BASE/200ML (EQ 0.2MG BASE/ML) | N20343 | 003 | Aug 09, 1994 | Jun | CPOT |
| >A> | AP | + AP + | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | N20343 | 003 | Aug 09, 1994 | Jun | CPOT |
| | | EQ 20MG BASE/200ML (EQ 0.2MG BASE/ML) | N20343 | 003 | Aug 09, 1994 | May | CDFR | |
| | | EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML) | N20343 | 004 | Aug 09, 1994 | May | CDFR | |

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCIN

| | | | | | | | | |
|-----|----|---------------------------|---------------|--------|-----|--------------|-----|------|
| >D> | AB | TRIAZ PHARMS | EQ 50MG BASE | N50649 | 001 | May 31, 1990 | Jun | CAHN |
| >D> | | @ | EQ 75MG BASE | N50649 | 003 | Feb 12, 2001 | Jun | CAHN |
| >D> | AB | | EQ 100MG BASE | N50649 | 002 | May 31, 1990 | Jun | CAHN |
| >A> | AB | TRIAZ PHARMS LLC | EQ 50MG BASE | N50649 | 001 | May 31, 1990 | Jun | CAHN |
| >A> | | @ | EQ 75MG BASE | N50649 | 003 | Feb 12, 2001 | Jun | CAHN |
| >A> | AB | | EQ 100MG BASE | N50649 | 002 | May 31, 1990 | Jun | CAHN |
| | | MINOCYCLINE HYDROCHLORIDE | | | | | | |
| | AB | AUROBINDO PHARMA | EQ 50MG BASE | N65470 | 001 | Mar 11, 2008 | Feb | NEWA |
| | AB | | EQ 75MG BASE | N65470 | 002 | Mar 11, 2008 | Feb | NEWA |
| | AB | | EQ 100MG BASE | N65470 | 003 | Mar 11, 2008 | Feb | NEWA |
| | AB | + TEVA | EQ 100MG BASE | N63009 | 001 | Mar 02, 1992 | Apr | CRLD |
| | AB | | EQ 100MG BASE | N63009 | 001 | Mar 02, 1992 | Feb | CRLD |

INJECTABLE; INJECTION

MINOCIN

| | | | | | | | | |
|-----|--|--------------------|--------------------|--------|-----|--|-----|------|
| >D> | | @ TRIAX PHARMS | EQ 100MG BASE/VIAL | N50444 | 001 | | Jun | CAHN |
| >A> | | @ TRIAX PHARMS LLC | EQ 100MG BASE/VIAL | N50444 | 001 | | Jun | CAHN |

TABLET; ORAL

MINOCYCLINE HYDROCHLORIDE

| | | | | | | | |
|----|--------------------|---------------|--------|-----|--------------|-----|------|
| AB | DR REDDYS LABS LTD | EQ 50MG BASE | N65436 | 001 | Dec 26, 2007 | Feb | CAHN |
| AB | | EQ 75MG BASE | N65436 | 002 | Dec 26, 2007 | Feb | CAHN |
| AB | | EQ 100MG BASE | N65436 | 003 | Dec 26, 2007 | Feb | CAHN |

MINOXIDIL

TABLET; ORAL

LONITEN

| | | | | | | |
|------------------------|-------|--------|-----|--|-----|------|
| @ PHARMACIA AND UPJOHN | 2.5MG | N18154 | 001 | | Jan | DISC |
| @ | 10MG | N18154 | 003 | | Jan | DISC |

MINOXIDIL

| | | | | | | | |
|----|---------------|------|--------|-----|--------------|-----|------|
| AB | + WATSON LABS | 10MG | N71345 | 001 | Mar 03, 1987 | Mar | CRLD |
|----|---------------|------|--------|-----|--------------|-----|------|

MIRTAZAPINE

TABLET; ORAL

MIRTAZAPINE

| | | | | | | | | |
|-----|----|--------|------|--------|-----|--------------|-----|------|
| >D> | AB | ROXANE | 15MG | N76270 | 001 | Jun 19, 2003 | Jun | DISC |
| >A> | | @ | 15MG | N76270 | 001 | Jun 19, 2003 | Jun | DISC |
| >D> | AB | | 30MG | N76270 | 002 | Jun 19, 2003 | Jun | DISC |

TABLET; ORAL

MIRTAZAPINE

| | | | |
|--------|----------|------|----------------------------------|
| >A> | @ ROXANE | 30MG | N76270 002 Jun 19, 2003 Jun DISC |
| >D> AB | | 45MG | N76270 003 Jun 19, 2003 Jun DISC |
| >A> | @ | 45MG | N76270 003 Jun 19, 2003 Jun DISC |

MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

MITOXANTRONE HYDROCHLORIDE

| | | | |
|------------|--------------------|------------------------------|----------------------------------|
| AP | DABUR ONCOLOGY PLC | EQ 20MG BASE/10ML (2MG/ML) | N78606 001 May 14, 2008 Apr NEWA |
| AP | | EQ 25MG BASE/12.5ML (2MG/ML) | N78606 002 May 14, 2008 Apr NEWA |
| AP | | EQ 30MG BASE/15ML (2MG/ML) | N78606 003 May 14, 2008 Apr NEWA |
| NOVANTRONE | | | |
| >D> AP | + EMD SERONO | EQ 25MG BASE/12.5ML (2MG/ML) | N19297 002 Dec 23, 1987 Jun DISC |
| >A> | @ | EQ 25MG BASE/12.5ML (2MG/ML) | N19297 002 Dec 23, 1987 Jun DISC |
| >D> AP | + | EQ 30MG BASE/15ML (2MG/ML) | N19297 003 Dec 23, 1987 Jun DISC |
| >A> | @ | EQ 30MG BASE/15ML (2MG/ML) | N19297 003 Dec 23, 1987 Jun DISC |

MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

MOEXIPRIL HYDROCHLORIDE

| | | | |
|----|------------|-------|----------------------------------|
| AB | APOTEX INC | 7.5MG | N78454 001 Jun 02, 2008 May NEWA |
| AB | | 15MG | N78454 002 Jun 02, 2008 May NEWA |

MOMETASONE FUBROATE

CREAM; TOPICAL

MOMETASONE FUBROATE

| | | | |
|----|-------------------|------|----------------------------------|
| AB | GLENMARK GENERICS | 0.1% | N78541 001 May 28, 2008 May NEWA |
|----|-------------------|------|----------------------------------|

OINTMENT; TOPICAL

MOMETASONE FUBROATE

| | | | |
|----|-------------------|------|----------------------------------|
| AB | GLENMARK GENERICS | 0.1% | N78571 001 May 28, 2008 May NEWA |
|----|-------------------|------|----------------------------------|

POWDER; INHALATION

ASMANEX TWISTHALER

SCHERING

0.11MG/INH

N21067 002 Feb 01, 2008 Feb NEWA

MORPHINE SULFATE

SOLUTION; ORAL

MORPHINE SULFATE

ROXANE

10MG/5ML

N22195 001 Mar 17, 2008 Mar NEWA

+

20MG/5ML

N22195 002 Mar 17, 2008 Mar NEWA

TABLET; ORAL

MORPHINE SULFATE

ROXANE

15MG

N22207 001 Mar 17, 2008 Mar NEWA

+

30MG

N22207 002 Mar 17, 2008 Mar NEWA

TABLET, EXTENDED RELEASE; ORAL

MS CONTIN

| | | | |
|----|------------------|-------|----------------------------------|
| AB | PURDUE PHARMA LP | 15MG | N19516 003 Sep 12, 1989 May CAHN |
| AB | | 30MG | N19516 001 May 29, 1987 May CAHN |
| AB | + | 60MG | N19516 002 Apr 08, 1988 May CAHN |
| AB | | 100MG | N19516 004 Jan 16, 1990 May CAHN |
| AB | | 200MG | N19516 005 Nov 08, 1993 May CAHN |

MUPIROCIN

OINTMENT; TOPICAL

CENTANY

| | | | |
|----|-----------------|----|----------------------------------|
| BX | ORTHONEUTROGENA | 2% | N50788 001 Dec 04, 2002 Feb CAHN |
|----|-----------------|----|----------------------------------|

NABUMETONE

TABLET; ORAL

NABUMETONE

| | | | |
|----|----------------|-------|----------------------------------|
| AB | INVAGEN PHARMS | 500MG | N78671 001 Mar 07, 2008 Feb NEWA |
| AB | | 750MG | N78671 002 Mar 07, 2008 Feb NEWA |

>D> NALMEFENE HYDROCHLORIDE

>D> INJECTABLE; INJECTION

>D> REVEX

| | | | |
|-----|------------------------|------------------|----------------------------------|
| >D> | + BAXTER HLTHCARE CORP | EQ 0.1MG BASE/ML | N20459 001 Apr 17, 1995 Jun DISC |
| >A> | @ | EQ 0.1MG BASE/ML | N20459 001 Apr 17, 1995 Jun DISC |
| >D> | + | EQ 1MG BASE/ML | N20459 002 Apr 17, 1995 Jun DISC |
| >A> | @ | EQ 1MG BASE/ML | N20459 002 Apr 17, 1995 Jun DISC |

NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE

TABLET; ORAL

TREXIMET

| | | |
|-------------------|--------------------|----------------------------------|
| + GLAXOSMITHKLINE | 500MG;EQ 85MG BASE | N21926 001 Apr 15, 2008 May CAHN |
| + POZEN | 500MG;EQ 85MG BASE | N21926 001 Apr 15, 2008 Apr NEWA |

NEBIVOLOL HYDROCHLORIDE

TABLET; ORAL

BYSTOLIC

| | | |
|-------------|---------------|----------------------------------|
| FOREST LABS | EQ 2.5MG BASE | N21742 002 Dec 17, 2007 May CAHN |
| | EQ 5MG BASE | N21742 003 Dec 17, 2007 May CAHN |
| + | EQ 10MG BASE | N21742 004 Dec 17, 2007 May CAHN |

NEFAZODONE HYDROCHLORIDE

TABLET; ORAL

NEFAZODONE HYDROCHLORIDE

| | | | |
|--------|--------------------|-------|----------------------------------|
| >D> AB | DR REDDYS LABS INC | 50MG | N76309 001 Sep 16, 2003 Jun CTEC |
| >A> BX | | 50MG | N76309 001 Sep 16, 2003 Jun CTEC |
| >D> AB | | 100MG | N76309 002 Sep 16, 2003 Jun CTEC |
| >A> BX | | 100MG | N76309 002 Sep 16, 2003 Jun CTEC |
| >D> AB | | 150MG | N76309 003 Sep 16, 2003 Jun CTEC |
| >A> BX | | 150MG | N76309 003 Sep 16, 2003 Jun CTEC |
| >D> AB | | 200MG | N76309 004 Sep 16, 2003 Jun CTEC |
| >A> BX | | 200MG | N76309 004 Sep 16, 2003 Jun CTEC |
| >D> AB | | 250MG | N76309 005 Sep 16, 2003 Jun CTEC |
| >A> BX | | 250MG | N76309 005 Sep 16, 2003 Jun CTEC |

NIACIN; SIMVASTATIN

TABLET, EXTENDED RELEASE; ORAL

SIMCOR

| | | |
|--------|------------|----------------------------------|
| ABBOTT | 500MG;20MG | N22078 001 Feb 15, 2008 Feb NEWA |
| | 750MG;20MG | N22078 002 Feb 15, 2008 Feb NEWA |
| + | 1GM;20MG | N22078 003 Feb 15, 2008 Feb NEWA |

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL

CARDENE

| | | | |
|----|---------------------------|------|----------------------------------|
| AB | EKR THERAP | 20MG | N19488 001 Dec 21, 1988 Apr CAHN |
| AB | + | 30MG | N19488 002 Dec 21, 1988 Apr CAHN |
| | NICARDIPINE HYDROCHLORIDE | | |
| AB | AMNEAL PHARM | 20MG | N74928 001 Mar 19, 1998 Feb CAHN |

CAPSULE; ORAL

NICARDIPINE HYDROCHLORIDE

| | | | |
|---------------------------------|--------------|----------------------------------|----------------------------------|
| AB | AMNEAL PHARM | 30MG | N74928 002 Mar 19, 1998 Feb CAHN |
| CAPSULE, EXTENDED RELEASE; ORAL | | | |
| CARDENE SR | | | |
| + EKR THERAP | 30MG | N20005 001 Feb 21, 1992 Apr CAHN | |
| + | 45MG | N20005 002 Feb 21, 1992 Apr CAHN | |
| + | 60MG | N20005 003 Feb 21, 1992 Apr CAHN | |
| INJECTABLE; INJECTION | | | |
| CARDENE | | | |
| + EKR THERAP | 2.5MG/ML | N19734 001 Jan 30, 1992 Apr CAHN | |

NIFEDIPINETABLET, EXTENDED RELEASE; ORAL
NIFEDIPINE

| | | | |
|---------|----------------|------|----------------------------------|
| >D> AB2 | MARTEC USA LLC | 90MG | N75414 003 Mar 23, 2004 Jun CTEC |
| >A> BX | | 90MG | N75414 003 Mar 23, 2004 Jun CTEC |

NIMODIPINECAPSULE; ORAL
NIMODIPINE

| | | | |
|----|-------------------|------|----------------------------------|
| AB | BANNER PHARMACAPS | 30MG | N76740 001 Jan 17, 2008 Jan NEWA |
|----|-------------------|------|----------------------------------|

NISOLDIPINETABLET, EXTENDED RELEASE; ORAL
SULAR

| | | |
|---------------------|--------|----------------------------------|
| + SCIELE PHARMA INC | 8.5MG | N20356 008 Jan 02, 2008 Jan NEWA |
| + | 17MG | N20356 007 Jan 02, 2008 Jan NEWA |
| | | N20356 006 Jan 02, 2008 Jan NEWA |
| + | 25.5MG | N20356 005 Jan 02, 2008 Jan NEWA |
| | | N20356 004 Jan 02, 2008 Jan NEWA |
| + | 34MG | |

NITROFURAZONE

OINTMENT; TOPICAL

NITROFURAZONE

| | | | |
|--------|------|------------|----------|
| @ TARO | 0.2% | N86156 001 | Jan DISC |
|--------|------|------------|----------|

NORETHINDRONE

TABLET; ORAL-28

MICRONOR

| | | | |
|------------------------------|--------|------------|----------|
| >A> AB2 + ORTHO MCNEIL | 0.35MG | N16954 001 | Jun CAHN |
| >D> AB2 + ORTHO MCNEIL PHARM | 0.35MG | N16954 001 | Jun CAHN |

NYSTATIN

SUSPENSION; ORAL

NILSTAT

| | | | |
|------------------------|------------------|----------------------------------|----------|
| AA + GLENMARK GENERICS | 100,000 UNITS/ML | N50299 001 | Apr CAHN |
| TABLET; ORAL | | | |
| NYSTATIN | | | |
| AA + TEVA | 500,000 UNITS | N62506 001 Jan 16, 1984 Jan CRLD | |

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

| | | |
|------------------|-------------------|----------------------------------|
| AP + BEDFORD | EQ 0.2MG BASE/ML | N76330 001 Apr 08, 2005 Jan CRLD |
| AP + | EQ 1MG BASE/ML | N76330 002 Apr 08, 2005 Jan CRLD |
| AP SUN PHARM IND | EQ 0.05MG BASE/ML | N77329 001 Mar 04, 2008 Feb NEWA |

INJECTABLE; INJECTION

| | | | |
|----|-------------------------------------|------------------|----------------------------------|
| AP | OCTREOTIDE ACETATE SUN PHARM IND | EQ 0.1MG BASE/ML | N77329 002 Mar 04, 2008 Feb NEWA |
| AP | | EQ 0.2MG BASE/ML | N77330 001 Mar 04, 2008 Feb NEWA |
| AP | | EQ 0.5MG BASE/ML | N77329 003 Mar 04, 2008 Feb NEWA |
| AP | | EQ 1MG BASE/ML | N77331 001 Mar 04, 2008 Feb NEWA |

OFLOXACININJECTABLE; INJECTION

| | | |
|---|---------|----------------------------------|
| OFLOXACIN @ BEDFORD | 40MG/ML | N75762 001 Jan 16, 2002 Apr DISC |
| SOLUTION/DROPS; OPHTHALMIC OFLOXACIN AT AKORN | 0.3% | N76407 001 Apr 15, 2008 Mar NEWA |
| SOLUTION/DROPS; OTIC OFLOXACIN AT ALCON | 0.3% | N78222 001 Mar 17, 2008 Mar NEWA |
| AT BAUSCH AND LOMB | 0.3% | N76128 001 Mar 17, 2008 Mar NEWA |
| AT HI TECH PHARMA | 0.3% | N76616 001 Mar 17, 2008 Mar NEWA |

TABLET; ORAL

| | | |
|-------------------------------|-------|----------------------------------|
| FLOXIN >A> AB ORTHO MCNEIL | 200MG | N19735 001 Dec 28, 1990 Jun CAHN |
| | 300MG | N19735 002 Dec 28, 1990 Jun CAHN |
| | 400MG | N19735 003 Dec 28, 1990 Jun CAHN |
| >D> AB ORTHO MCNEIL PHARM | 200MG | N19735 001 Dec 28, 1990 Jun CAHN |
| >D> AB | 300MG | N19735 002 Dec 28, 1990 Jun CAHN |
| >D> AB | 400MG | N19735 003 Dec 28, 1990 Jun CAHN |

OLOPATADINE HYDROCHLORIDESOLUTION/DROPS; OPHTHALMIC

| | | |
|--|---------------|----------------------------------|
| PATADAY + ALCON | EQ 0.2% BASE | N21545 001 Dec 22, 2004 Apr CPOT |
| SPRAY, METERED; NASAL PATANASE + ALCON | 0.665MG/SPRAY | N21861 001 Apr 15, 2008 Apr NEWA |

OMEGA-3-ACID ETHYL ESTERSCAPSULE; ORAL

| | | |
|------------------------------------|-----|----------------------------------|
| LOVAZA >D> + RELIANT PHARMS INC | 1GM | N21654 001 Nov 10, 2004 Jun CAHN |
| >A> + SMITHKLINE BEECHAM | 1GM | N21654 001 Nov 10, 2004 Jun CAHN |

OMEPRAZOLECAPSULE, DELAYED REL PELLETS; ORAL

| | | |
|-------------------------------|------|----------------------------------|
| OMEPRAZOLE AB ANDRX PHARMS | 10MG | N75347 001 May 30, 2008 May NEWA |
| AB | 20MG | N75347 002 May 30, 2008 May NEWA |
| AB | 40MG | N75347 003 May 30, 2008 Feb NEWA |
| PRILOSEC AB + ASTRAZENECA | 40MG | N19810 002 Jan 15, 1998 May CFTG |

OMEPRAZOLE MAGNESIUMFOR SUSPENSION, DELAYED RELEASE; ORALPRILOSEC

| | | |
|------------------------------|----------------------|----------------------------------|
| ASTRAZENECA + ASTRAZENECA | EQ 2.5MG BASE/PACKET | N22056 001 Mar 20, 2008 Mar NEWA |
| | EQ 10MG BASE/PACKET | N22056 002 Mar 20, 2008 Mar NEWA |

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

| | | | | | | | |
|---|---------------------|-------------------|--------|-----|--------------|-----|------|
| AP | AKORN STRIDES | EQ 2MG BASE/ML | N78257 | 001 | Apr 23, 2008 | Apr | NEWA |
| ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER | | | | | | | |
| AP | CLARIS LIFESCIENCES | EQ 0.64MG BASE/ML | N78308 | 001 | Mar 17, 2008 | Mar | NEWA |
| ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE | | | | | | | |
| AP | AKORN STRIDES | EQ 2MG BASE/ML | N78244 | 001 | Apr 23, 2008 | Apr | NEWA |
| AP | TARO PHARMS IRELAND | EQ 2MG BASE/ML | N78014 | 001 | Mar 21, 2008 | Mar | NEWA |

OXCARBAZEPINE

TABLET; ORAL

OXCARBAZEPINE

| | | | | | | | |
|----|------------|-------|--------|-----|--------------|-----|------|
| AB | APOTEX INC | 150MG | N77747 | 001 | Apr 09, 2008 | Mar | NEWA |
| AB | | 300MG | N77747 | 002 | Apr 09, 2008 | Mar | NEWA |
| AB | | 600MG | N77747 | 003 | Apr 09, 2008 | Mar | NEWA |

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

| | | | | | | | |
|---------------------|-----------------|---------|--------|-----|--------------|-----|------|
| >D> | DITROPAN | | | | | | |
| >D> | AA + ALZA | 5MG/5ML | N18211 | 001 | | Jun | DISC |
| >A> | @ | 5MG/5ML | N18211 | 001 | | Jun | DISC |
| OXYBUTYNIN CHLORIDE | | | | | | | |
| >D> | AA MORTON GROVE | 5MG/5ML | N74868 | 001 | Feb 12, 1997 | Jun | CRLD |
| >A> | AA + | 5MG/5ML | N74868 | 001 | Feb 12, 1997 | Jun | CRLD |

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OXYCODONE HYDROCHLORIDE

| | | | | | | | |
|------------------|------|--------|-----|--------------|-----|------|--|
| @ IMPAX LABS | 80MG | N76318 | 001 | Sep 27, 2004 | Feb | DISC | |
| @ IMPAX PHARMS | 10MG | N76446 | 001 | Dec 06, 2005 | Feb | DISC | |
| @ | 20MG | N76446 | 002 | Dec 06, 2005 | Feb | DISC | |
| @ | 40MG | N76446 | 003 | Dec 06, 2005 | Feb | DISC | |
| @ TEVA | 10MG | N76610 | 001 | Dec 06, 2005 | Feb | DISC | |
| @ | 20MG | N76610 | 002 | Dec 06, 2005 | Feb | DISC | |
| @ | 40MG | N76610 | 003 | Dec 06, 2005 | Feb | DISC | |
| @ | 80MG | N76168 | 001 | Mar 23, 2004 | Feb | DISC | |
| OXYCONTIN | | | | | | | |
| PURDUE PHARMA LP | 10MG | N20553 | 001 | Dec 12, 1995 | Feb | CTEC | |
| | 15MG | N20553 | 006 | Sep 18, 2006 | Jan | CMFD | |
| | 20MG | N20553 | 002 | Dec 12, 1995 | Feb | CTEC | |
| | 30MG | N20553 | 007 | Sep 18, 2006 | Jan | CMFD | |
| + | 40MG | N20553 | 003 | Dec 12, 1995 | Feb | CTEC | |
| | 60MG | N20553 | 008 | Sep 18, 2006 | Jan | CMFD | |
| | 80MG | N20553 | 004 | Jan 06, 1997 | Feb | CTEC | |

OXYMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OPANA ER

| | | | | | | |
|-------------|-------|--------|-----|--------------|-----|------|
| ENDO PHARMS | 7.5MG | N21610 | 005 | Feb 29, 2008 | Feb | NEWA |
| | 15MG | N21610 | 006 | Feb 29, 2008 | Feb | NEWA |
| | 30MG | N21610 | 007 | Feb 29, 2008 | Feb | NEWA |

OXYTETRACYCLINE HYDROCHLORIDE

| | | | |
|---|---------------|------------|----------|
| CAPSULE; ORAL TERRAMYCIN @ PFIZER | EQ 250MG BASE | N50286 002 | Mar DISC |
|---|---------------|------------|----------|

OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

| | | | |
|--|-------------------------------------|------------|-----------------------|
| AP + APP PHARMS | 100USP UNITS/10 ML (10USP UNITS/ML) | N18248 002 | Jan CFTG |
| AP + BAXTER HLTHCARE CORP | 100USP UNITS/10ML (10USP UNITS/ML) | N18243 002 | Jan 10, 2007 Mar CDER |
| AP TEVA PARENTERAL | 10USP UNITS/ML (10USP UNITS/ML) | N77453 001 | Jan 24, 2008 Jan NEWA |
| AP | 100USP UNITS/10ML (10USP UNITS/ML) | N77453 002 | Jan 24, 2008 Jan NEWA |
| PITOCIN | | | |
| AP JHP PHARMS | 100USP UNITS/10ML (10USP UNITS/ML) | N18261 002 | Jul 27, 2007 May NEWA |
| INJECTABLE; INTRAMUSCULAR, IV (INFUSION) | | | |
| OXYTOCIN | | | |
| AP + BAXTER HLTHCARE CORP | 100USP UNITS/10ML (10USP UNITS/ML) | N18243 002 | Jan 10, 2007 Feb NEWA |

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

ABRAXANE

| | | | |
|--------------------------|------------|------------|-----------------------|
| >D> + ABRAXIS BIOSCIENCE | 100MG/VIAL | N21660 001 | Jan 07, 2005 Jun CAHN |
| >A> + | 100MG/VIAL | N21660 001 | Jan 07, 2005 Jun CAHN |
| INJECTABLE; INJECTION | | | |
| PACLITAXEL | | | |
| AP PLIVA LACHEMA | 6MG/ML | N77413 001 | Mar 12, 2008 Feb NEWA |

PALIPERIDONE

TABLET, EXTENDED RELEASE; ORAL

INVEGA

| | | | |
|------------------|------|------------|-----------------------|
| >D> JANSSEN LP | 3MG | N21999 001 | Dec 19, 2006 Jun CAHN |
| >D> + | 6MG | N21999 002 | Dec 19, 2006 Jun CAHN |
| + + | 6MG | N21999 002 | Dec 19, 2006 Jan CRLD |
| >D> | 9MG | N21999 003 | Dec 19, 2006 Jun CAHN |
| | 9MG | N21999 003 | Dec 19, 2006 Jan CRLD |
| >D> @ | 12MG | N21999 004 | Dec 19, 2006 Jun CAHN |
| >A> ORTHO MCNEIL | 3MG | N21999 001 | Dec 19, 2006 Jun CAHN |
| >A> + | 6MG | N21999 002 | Dec 19, 2006 Jun CAHN |
| >A> | 9MG | N21999 003 | Dec 19, 2006 Jun CAHN |
| >A> @ | 12MG | N21999 004 | Dec 19, 2006 Jun CAHN |

PALONOSETRON HYDROCHLORIDE

INJECTABLE; INTRAVENOUS

ALOXI

| | | | |
|------------------|---|------------|-----------------------|
| HELSINN HLTHCARE | EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML) | N21372 002 | Feb 29, 2008 Feb NEWA |
| + | EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML) | N21372 001 | Jul 25, 2003 Feb CPOT |

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAROXETINE HYDROCHLORIDE

| | | | |
|----------|--------------|------------|-----------------------|
| AB MYLAN | EQ 10MG BASE | N78902 001 | Mar 13, 2008 Mar NEWA |
|----------|--------------|------------|-----------------------|

TABLET; ORAL

PAROXETINE HYDROCHLORIDE

| | | | | | | | |
|-----|-------|--------------|--------------|--------------|--------------|------|------|
| AB | MYLAN | EQ 20MG BASE | N78902 002 | Mar 13, 2008 | Mar | NEWA | |
| AB | | EQ 30MG BASE | N78902 003 | Mar 13, 2008 | Mar | NEWA | |
| AB | | EQ 40MG BASE | N78902 004 | Mar 13, 2008 | Mar | NEWA | |
| >D> | AB | ROXANE | EQ 10MG BASE | N78026 001 | Jun 29, 2007 | Jun | DISC |
| >A> | @ | | EQ 10MG BASE | N78026 001 | Jun 29, 2007 | Jun | DISC |
| >D> | AB | | EQ 20MG BASE | N78026 002 | Jun 29, 2007 | Jun | DISC |
| >A> | @ | | EQ 20MG BASE | N78026 002 | Jun 29, 2007 | Jun | DISC |
| >D> | AB | | EQ 30MG BASE | N78026 003 | Jun 29, 2007 | Jun | DISC |
| >A> | @ | | EQ 30MG BASE | N78026 003 | Jun 29, 2007 | Jun | DISC |
| >D> | AB | | EQ 40MG BASE | N78026 004 | Jun 29, 2007 | Jun | DISC |
| >A> | @ | | EQ 40MG BASE | N78026 004 | Jun 29, 2007 | Jun | DISC |

PAROXETINE MESYLATE

TABLET; ORAL

PEXEVA

| | | | | | | |
|-----|--------------|--------------|------------|--------------|-----|------|
| >D> | JDS PHARMS | EQ 10MG BASE | N21299 001 | Jul 03, 2003 | Jun | CAHN |
| >D> | | EQ 20MG BASE | N21299 002 | Jul 03, 2003 | Jun | CAHN |
| >D> | | EQ 30MG BASE | N21299 003 | Jul 03, 2003 | Jun | CAHN |
| >D> | + | EQ 40MG BASE | N21299 004 | Jul 03, 2003 | Jun | CAHN |
| >A> | NOVEN THERAP | EQ 10MG BASE | N21299 001 | Jul 03, 2003 | Jun | CAHN |
| >A> | | EQ 20MG BASE | N21299 002 | Jul 03, 2003 | Jun | CAHN |
| >A> | | EQ 30MG BASE | N21299 003 | Jul 03, 2003 | Jun | CAHN |
| >A> | + | EQ 40MG BASE | N21299 004 | Jul 03, 2003 | Jun | CAHN |

PENICILLAMINE

TABLET; ORAL

DEPEN

| | | | | | | |
|-----|---|---------------------|-------|------------|-----|------|
| >A> | + | MEDA PHARMS | 250MG | N19854 001 | Jun | CAHN |
| >D> | + | MEDPOINTE PHARM HLC | 250MG | N19854 001 | Jun | CAHN |

PENICILLIN V POTASSIUM

TABLET; ORAL

PENICILLIN V POTASSIUM

| | | | | | | |
|----|------------------|---------------|------------|--------------|-----|------|
| AB | AUROBINDO PHARMA | EQ 250MG BASE | N65435 001 | Apr 29, 2008 | Apr | NEWA |
| AB | | EQ 500MG BASE | N65435 002 | Apr 29, 2008 | Apr | NEWA |

PENTOSAN POLYSULFATE SODIUM

CAPSULE; ORAL

ELMIRON

| | | | | | | | |
|-----|---|--------------------|-------|------------|--------------|-----|------|
| >A> | + | ORTHO MCNEIL | 100MG | N20193 001 | Sep 26, 1996 | Jun | CAHN |
| >D> | + | ORTHO MCNEIL PHARM | 100MG | N20193 001 | Sep 26, 1996 | Jun | CAHN |

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

| | | | | | | |
|----|--------|------|------------|--------------|-----|------|
| AB | SANDOZ | 2MG | N89683 001 | Dec 08, 1988 | May | CMFD |
| AB | | 4MG | N89684 001 | Dec 08, 1988 | May | CMFD |
| AB | | 8MG | N89685 001 | Dec 08, 1988 | May | CMFD |
| AB | | 16MG | N89686 001 | Dec 08, 1988 | May | CMFD |

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

| | | | | | | | |
|-----|----|---|--------|------|------------|-----|------|
| >D> | AA | + | SANDOZ | 35MG | N85695 001 | Jun | CTEC |
|-----|----|---|--------|------|------------|-----|------|

CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

| | | | | | |
|--------|----------------|------|------------|--------------|----------|
| >A> | + SANDOZ | 35MG | N85695 001 | Jun | CTEC |
| >D> | X-TROZINE | | | | |
| >D> AA | SHIRE RICHWOOD | 35MG | N87394 001 | Sep 22, 1982 | Jun DISC |
| >A> | @ | 35MG | N87394 001 | Sep 22, 1982 | Jun DISC |

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | |
|--------|----------------|-------|------------|--------------|----------|
| >D> | X-TROZINE L.A. | | | | |
| >D> BC | SHIRE RICHWOOD | 105MG | N87371 001 | Aug 24, 1982 | Jun DISC |
| >A> | @ | 105MG | N87371 001 | Aug 24, 1982 | Jun DISC |

TABLET; ORAL

DI-METREX

@ PVT FORM 35MG

N85698 001 Apr CAHN

PHENDIMETRAZINE TARTRATE

| | | | | | |
|----|----------------|------|------------|--------------|----------|
| AA | ACTAVIS TOTOWA | 35MG | N40762 001 | Jan 28, 2008 | Mar CAHN |
| AA | AMIDE PHARM | 35MG | N40762 001 | Jan 28, 2008 | Jan NEWA |
| | @ PVT FORM | 35MG | N85199 001 | | Apr CAHN |
| | @ | 35MG | N85697 001 | | Apr CAHN |

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HYDROCHLORIDE

| | | | | | |
|----|----------|--------|------------|--------------|----------|
| AA | KVK TECH | 15MG | N40886 002 | Mar 31, 2008 | Mar NEWA |
| AA | | 30MG | N40875 001 | Mar 21, 2008 | Mar NEWA |
| AA | | 30MG | N40886 001 | Mar 31, 2008 | Mar NEWA |
| AA | | 37.5MG | N40887 001 | Apr 24, 2008 | Apr NEWA |

TABLET; ORAL

PHENTERMINE HYDROCHLORIDE

| | | | | | |
|----|----------------|--------|------------|--------------|----------|
| AA | KVK TECH | 37.5MG | N40876 001 | Mar 31, 2008 | Mar NEWA |
| AA | VINTAGE PHARMS | 37.5MG | N40377 001 | Jan 04, 2002 | May CDFR |

PHENTOLAMINE MESYLATE

INJECTABLE; INJECTION

ORAVERSE

+ NOVALAR 0.4MG/1.7ML

N22159 001 May 09, 2008 May NEWA

PHENYL AMINOSALICYLATE

POWDER; ORAL

PHENY-PAS-TEBAMIN

@ PHARM RES ASSOC 50%

N11695 002 May CAHN

TABLET; ORAL

PHENY-PAS-TEBAMIN

@ PHARM RES ASSOC 500MG

N11695 003 May CAHN

PHENYTOIN SODIUM

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

| | | | | | |
|----|---------------|----------------|------------|--------------|----------|
| AB | WOCKHARDT USA | 100MG EXTENDED | N40732 001 | Jan 30, 2008 | Jan NEWA |
|----|---------------|----------------|------------|--------------|----------|

INJECTABLE; INJECTION

PHENYTOIN SODIUM

| | | | | | |
|----|----------|---------|------------|--|--|
| AP | + BAXTER | 50MG/ML | N84307 001 | | |
|----|----------|---------|------------|--|--|

Mar CAHN

PHENYTOIN SODIUM, EXTENDED

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

| | | | | | |
|--------|----------------|----------------|------------|--------------|----------|
| >A> AB | SUN PHARM INDs | 200MG EXTENDED | N40731 001 | Jun 30, 2008 | Jun NEWA |
|--------|----------------|----------------|------------|--------------|----------|

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

>A> AB SUN PHARM INDS 300MG EXTENDED N40731 002 Jun 30, 2008 Jun NEWA

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL

SALAGEN

>A> AB EISAI MEDCL RES 5MG N20237 001 Mar 22, 1994 Jun CAHN

>A> AB + 7.5MG N20237 002 Apr 18, 2003 Jun CAHN

>D> AB MGI PHARMA INC 5MG N20237 001 Mar 22, 1994 Jun CAHN

>D> AB + 7.5MG N20237 002 Apr 18, 2003 Jun CAHN

POLYTHIAZIDE

>D> TABLET; ORAL

>D> RENESE

>D> PFIZER 1MG N12845 001 Jun DISC

>A> @ 1MG N12845 001 Jun DISC

>D> 2MG N12845 002 Jun DISC

>A> @ 2MG N12845 002 Jun DISC

>D> + 4MG N12845 003 Jun DISC

>A> @ 4MG N12845 003 Jun DISC

POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE

>D> CAPSULE; ORAL

>D> MINIZIDE

>D> PFIZER 0.5MG;EQ 1MG BASE N17986 001 Jun DISC

>A> @ 0.5MG;EQ 1MG BASE N17986 001 Jun DISC

>D> 0.5MG;EQ 2MG BASE N17986 002 Jun DISC

>A> @ 0.5MG;EQ 2MG BASE N17986 002 Jun DISC

>D> + 0.5MG;EQ 5MG BASE N17986 003 Jun DISC

>A> @ 0.5MG;EQ 5MG BASE N17986 003 Jun DISC

POLYTHIAZIDE; RESERPINE

>D> TABLET; ORAL

>D> RENESE-R

>D> + PFIZER 2MG;0.25MG N13636 001 Jun DISC

>A> @ 2MG;0.25MG N13636 001 Jun DISC

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

MICRO-K

AB KV PHARM 8MEQ N18238 001 May CTEC

POTASSIUM CHLORIDE

AB ANDRX PHARMS 8MEQ N77419 001 Jun 02, 2008 May NEWA

AB 10MEQ N77419 002 Jun 02, 2008 May NEWA

TABLET, EXTENDED RELEASE; ORAL

POTASSIUM CHLORIDE

AB SCHERING 10MEQ N19439 002 Jun 13, 1986 Jan CTNA

AB + 20MEQ N19439 001 Jun 13, 1986 Jan CTNA

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

MIRAPEX

AB BOEHRINGER INGELHEIM 0.125MG N20667 001 Jul 01, 1997 Feb CFTG

AB + 0.25MG N20667 002 Jul 01, 1997 Feb CFTG

AB 0.5MG N20667 006 Feb 12, 1998 Feb CFTG

TABLET; ORAL

MIRAPEX

| | | | | | | | |
|------------------------------------|----------------------|---------|--------|-----|--------------|-----|------|
| AB | BOEHRINGER INGELHEIM | 1MG | N20667 | 003 | Jul 01, 1997 | Feb | CFTG |
| AB | | 1.5MG | N20667 | 005 | Jul 01, 1997 | Feb | CFTG |
| PRAMIPEXOLE DIHYDROCHLORIDE | | | | | | | |
| AB | BARR | 0.125MG | N77724 | 001 | Feb 19, 2008 | Feb | NEWA |
| AB | | 0.25MG | N77724 | 002 | Feb 19, 2008 | Feb | NEWA |
| AB | | 0.5MG | N77724 | 003 | Feb 19, 2008 | Feb | NEWA |
| AB | | 1MG | N77724 | 004 | Feb 19, 2008 | Feb | NEWA |
| AB | | 1.5MG | N77724 | 005 | Feb 19, 2008 | Feb | NEWA |

PRAVASTATIN SODIUM

TABLET; ORAL

PRAVASTATIN SODIUM

| | | | | | | | |
|----|------------------|------|--------|-----|--------------|-----|------|
| AB | LEK PHARMS DD | 80MG | N77491 | 001 | Feb 11, 2008 | Jan | NEWA |
| AB | TEVA PHARMS | 80MG | N77793 | 001 | Jan 15, 2008 | Jan | NEWA |
| AB | ZYDUS PHARMS USA | 10MG | N77751 | 001 | Apr 30, 2008 | Apr | NEWA |
| AB | | 20MG | N77751 | 002 | Apr 30, 2008 | Apr | NEWA |
| AB | | 40MG | N77751 | 003 | Apr 30, 2008 | Apr | NEWA |
| AB | | 80MG | N77751 | 004 | Apr 30, 2008 | Apr | NEWA |

PRAZOSIN HYDROCHLORIDE

| | | | | | | | |
|-----|--------------------------------|-------|--------|-----|--------------|-----|------|
| >D> | TABLET, EXTENDED RELEASE; ORAL | | | | | | |
| >D> | MINIPRESS XL | | | | | | |
| >D> | + PFIZER | 2.5MG | N19775 | 001 | Jan 29, 1992 | Jun | DISC |
| >A> | @ | 2.5MG | N19775 | 001 | Jan 29, 1992 | Jun | DISC |
| >D> | + | 5MG | N19775 | 002 | Jan 29, 1992 | Jun | DISC |
| >A> | @ | 5MG | N19775 | 002 | Jan 29, 1992 | Jun | DISC |

PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

| | | | | | | | |
|------------|-----|--------|-----|--|--|--|--|
| @ PVT FORM | 5MG | N80211 | 001 | | | | |
|------------|-----|--------|-----|--|--|--|--|

Apr CAHN

PREDNISOLONE ACETATE

SUSPENSION; ORAL

FLO-PRED

| | | | | | | |
|------|------------------|--------|-----|--------------|-----|------|
| TARO | EQ 5MG BASE/5ML | N22067 | 001 | Jan 17, 2008 | Jan | NEWA |
| + | EQ 15MG BASE/5ML | N22067 | 002 | Jan 17, 2008 | Jan | NEWA |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PREDNISOLONE SODIUM PHOSPHATE

| | | | | | | |
|---------------|------------------|--------|-----|--------------|-----|------|
| + PHARM ASSOC | EQ 10MG BASE/5ML | N78465 | 001 | Mar 07, 2008 | Apr | CRLD |
| AA | EQ 10MG BASE/5ML | N78465 | 001 | Mar 07, 2008 | Feb | NEWA |
| | EQ 20MG BASE/5ML | N78988 | 001 | Jun 09, 2008 | May | NEWA |

PREDNISONE

TABLET; ORAL

PREDNISONE

| | | | | | | | |
|------------|------|--------|-----|--|--|--|--|
| @ PVT FORM | 20MG | N85151 | 001 | | | | |
|------------|------|--------|-----|--|--|--|--|

Apr CAHN

PRIMIDONE

TABLET; ORAL

PRIMIDONE

| | | | | | | | |
|----|--------------|------|--------|-----|--------------|-----|------|
| AB | AMNEAL PHARM | 50MG | N40866 | 001 | Apr 23, 2008 | Apr | NEWA |
|----|--------------|------|--------|-----|--------------|-----|------|

TABLET; ORAL

PRIMIDONE

| | | | |
|----|--------------|-------|----------------------------------|
| AB | AMNEAL PHARM | 250MG | N40866 002 Apr 23, 2008 Apr NEWA |
| AB | IMPAX LABS | 50MG | N40717 001 Feb 12, 2008 Jan NEWA |
| AB | | 250MG | N40717 002 Feb 12, 2008 Jan NEWA |

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

PROCAINAMIDE HYDROCHLORIDE

| | | | | |
|----|---|-----------|----------|----------------------------------|
| AP | + | HOSPIRA | 100MG/ML | N89069 001 Feb 12, 1986 May CRLD |
| AP | + | | 500MG/ML | N89070 001 Feb 12, 1986 May CRLD |
| | @ | | 500MG/ML | N89537 001 Aug 25, 1987 May DISC |
| | | PRONESTYL | | |
| | @ | APOTHECON | 100MG/ML | N07335 002 Apr DISC |
| | @ | | 500MG/ML | N07335 005 Apr DISC |

TABLET; ORAL

PRONESTYL

| | | | |
|---|-----------|-------|---------------------|
| @ | APOTHECON | 250MG | N17371 001 Apr DISC |
| @ | | 375MG | N17371 002 Apr DISC |
| @ | | 500MG | N17371 003 Apr DISC |

>D> TABLET, EXTENDED RELEASE; ORAL
 >D> PROCANBID
 >D> + KING PHARMS 500MG N20545 001 Jan 31, 1996 Jun DISC
 >A> @ 500MG N20545 001 Jan 31, 1996 Jun DISC
 >D> + 1GM N20545 002 Jan 31, 1996 Jun DISC
 >A> @ 1GM N20545 002 Jan 31, 1996 Jun DISC

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

| | | |
|-------------------|----------------|----------------------------------|
| @ TEVA PARENTERAL | EQ 5MG BASE/ML | N40505 001 May 30, 2003 Jan DISC |
|-------------------|----------------|----------------------------------|

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HYDROCHLORIDE

| | | | |
|----|--------------------|---------|----------------------------------|
| AP | HIKMA FARMACEUTICA | 25MG/ML | N40737 001 Apr 24, 2008 Apr NEWA |
| AP | | 50MG/ML | N40737 002 Apr 24, 2008 Apr NEWA |
| | @ HOSPIRA | 50MG/ML | N83838 002 Apr DISC |

TABLET; ORAL

PHENERGAN

| | | |
|--------------------|------|---------------------|
| @ WYETH PHARMS INC | 25MG | N07935 003 Feb DISC |
|--------------------|------|---------------------|

PROMETHAZINE HYDROCHLORIDE

| | | | |
|----|----------------|--------|----------------------------------|
| AB | ACTAVIS TOTOWA | 12.5MG | N40673 001 Mar 05, 2008 Feb NEWA |
| AB | | 25MG | N40673 002 Mar 05, 2008 Feb NEWA |
| AB | | 50MG | N40673 003 Mar 05, 2008 Feb NEWA |
| AB | IMPAX LABS | 12.5MG | N40724 001 Feb 12, 2008 Jan NEWA |
| AB | | 25MG | N40724 002 Feb 12, 2008 Jan NEWA |
| AB | | 50MG | N40791 001 May 20, 2008 May NEWA |
| | @ PVT FORM | 12.5MG | N83214 001 Apr CAHN |
| | @ | 25MG | N83658 001 Apr CAHN |
| AB | WATSON LABS | 25MG | N83426 001 Apr CTEC |
| AB | | 50MG | N83711 001 Apr CTEC |

PROPANTHELINE BROMIDE

TABLET; ORAL

| | | | | | | |
|--------|-----------------------|-------|------------|-----|------|--|
| >D> | PRO-BANTHINE | | | | | |
| >D> BP | + SHIRE | 7.5MG | N08732 003 | Jun | DISC | |
| >A> | @ | 7.5MG | N08732 003 | Jun | DISC | |
| >D> BP | + | 15MG | N08732 002 | Jun | DISC | |
| >A> | @ | 15MG | N08732 002 | Jun | DISC | |
| | PROPANTHELINE BROMIDE | | | | | |
| | @ PVT FORM | 15MG | N80977 001 | Apr | CAHN | |
| >D> BP | ROXANE | 7.5MG | N80927 001 | Jun | CRLD | |
| >A> | + | 7.5MG | N80927 001 | Jun | CRLD | |
| >D> BP | | 15MG | N80927 002 | Jun | CRLD | |
| >A> | + | 15MG | N80927 002 | Jun | CRLD | |

PROPOFOL

INJECTABLE; INJECTION

PROPOFOL

@ BEDFORD 10MG/ML

N74848 001 Apr 19, 2005 May DISC

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE

| | | | | |
|------------|------|------------|-----|------|
| @ PVT FORM | 32MG | N83464 001 | Apr | CAHN |
| @ | 65MG | N83113 001 | Apr | CAHN |

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL HYDROCHLORIDE

AP HIKMA FARMACEUTICA 1MG/ML N77760 001 Jan 31, 2008 Jan NEWA

TABLET; ORAL

INDERAL

| | | | | |
|------------------|------|------------|-----|------|
| @ AKRIMAX PHARMS | 10MG | N16418 001 | May | CAHN |
| @ | 20MG | N16418 003 | May | CAHN |

AB 40MG N16418 002 May CAHN

AB 60MG N16418 009 Oct 18, 1982 May CAHN

AB + 80MG N16418 004 May CAHN

@ 90MG N16418 010 Oct 18, 1982 May CAHN

PROPRANOLOL HYDROCHLORIDE

AB IPCA LABS LTD 10MG N78955 001 Jun 02, 2008 May NEWA

AB 20MG N78955 002 Jun 02, 2008 May NEWA

AB 40MG N78955 003 Jun 02, 2008 May NEWA

AB 60MG N78955 004 Jun 02, 2008 May NEWA

AB 80MG N78955 005 Jun 02, 2008 May NEWA

AB + PLIVA 80MG N71976 001 Apr 06, 1988 May CRLD

AB + 90MG N71977 001 Apr 06, 1988 May CRLD

PROTAMINE SULFATE

INJECTABLE; INJECTION

PROTAMINE SULFATE

+ APP PHARMS 10MG/ML N89454 001 Apr 07, 1987 May CAHN

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

ALLERFED

@ PVT FORM 60MG;2.5MG

N88860 001 Jan 31, 1985 Apr CAHN

QUETIAPINE FUMARATE

TABLET, EXTENDED RELEASE; ORAL
SEROQUEL XR
@ ASTRazeneca EQ 50MG BASE
+ EQ 200MG BASE
EQ 400MG BASE

| | | | | |
|--------|-----|--------------|-----|------|
| N22047 | 001 | May 17, 2007 | Apr | DISC |
| N22047 | 002 | May 17, 2007 | Mar | CRLD |
| N22047 | 004 | May 17, 2007 | Mar | CRLD |

QUINIDINE POLYGALACTURONATE

TABLET; ORAL
CARDIOQUIN
@ PHARM RES ASSOC 275MG

N11642 002 May CAHN

RAMIPRIL

| | |
|--------------------|--------|
| CAPSULE; ORAL | |
| RAMIPRIL | |
| ACTAVIS ELIZABETH | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| APOTEX | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| COBALT LABS INC | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| DR REDDYS LABS LTD | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| INVAGEN PHARMS | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| LUPIN | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| ROXANE | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| SANDOZ | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |
| TEVA PHARMS | 1.25MG |
| | 2.5MG |
| | 5MG |
| | 10MG |

RANITIDINE HYDROCHLORIDE

| | | | |
|-----------------------------|-------------------|----------------------|----------------------------------|
| GRANULE, EFFERVESCENT; ORAL | | | |
| ZANTAC 150 | | | |
| >D> | + GLAXOSMITHKLINE | EQ 150MG BASE/PACKET | N20251 002 Mar 31, 1994 Jun DISC |
| >A> | @ | EQ 150MG BASE/PACKET | N20251 002 Mar 31, 1994 Jun DISC |
| TABLET, EFFERVESCENT; ORAL | | | |
| ZANTAC 150 | | | |
| >D> | + GLAXOSMITHKLINE | EQ 150MG BASE | N20251 001 Mar 31, 1994 Jun DISC |
| >A> | @ | EQ 150MG BASE | N20251 001 Mar 31, 1994 Jun DISC |
| ZANTAC 25 | | | |
| >D> | GLAXOSMITHKLINE | EQ 25MG BASE | N20251 003 Apr 01, 2004 Jun CRLD |
| >A> | + | EQ 25MG BASE | N20251 003 Apr 01, 2004 Jun CRLD |

RAUWOLFIA SERPENTINA

| | | |
|----------------------|-------|---------------------|
| TABLET; ORAL | | |
| RAUWOLFIA SERPENTINA | | |
| @ PVT FORM | 50MG | N80583 001 Apr CAHN |
| @ | 100MG | N80583 002 Apr CAHN |

REGADENOSON

| | | |
|-----------------------|-----------------------|----------------------------------|
| INJECTABLE; INJECTION | | |
| LEXISCAN | | |
| + CV THERAP | 0.4MG/5ML (0.08MG/ML) | N22161 001 Apr 10, 2008 Apr NEWA |
| SOLUTION; INTRAVENOUS | | |
| LEXISCAN | | |
| >A> + ASTELLAS | 0.4MG/5ML (0.08MG/ML) | N22161 001 Apr 10, 2008 Jun CAHN |
| >D> + CV THERAP | 0.4MG/5ML (0.08MG/ML) | N22161 001 Apr 10, 2008 Jun CAHN |
| + | 0.4MG/5ML (0.08MG/ML) | N22161 001 Apr 10, 2008 May CDFR |

RESCINNAMINE

| | | |
|--------------|--------|---------------------|
| TABLET; ORAL | | |
| MODERIL | | |
| >D> PFIZER | 0.25MG | N10686 003 Jun DISC |
| >A> @ | 0.25MG | N10686 003 Jun DISC |
| >D> + | 0.5MG | N10686 006 Jun DISC |
| >A> @ | 0.5MG | N10686 006 Jun DISC |

RESERPINE

| | | |
|--------------|--------|---------------------|
| TABLET; ORAL | | |
| RESERPINE | | |
| @ PVT FORM | 0.1MG | N86117 001 Apr CAHN |
| @ | 0.25MG | N80582 001 Apr CAHN |
| @ | 0.25MG | N85775 001 Apr CAHN |
| @ | 1MG | N80582 002 Apr CAHN |

RIBAVIRIN

| | | |
|------------------|-------|----------------------------------|
| TABLET; ORAL | | |
| RIBAVIRIN | | |
| ZYDUS PHARMS USA | 500MG | N77094 004 Apr 18, 2008 Apr NEWA |

RIFAMPIN

| | | |
|---------------|-------|----------------------------------|
| CAPSULE; ORAL | | |
| RIFAMPIN | | |
| AB LANNETT | 150MG | N65390 001 Mar 28, 2008 Mar NEWA |
| AB | 300MG | N65390 002 Mar 28, 2008 Mar NEWA |

INJECTABLE; INJECTION

RIFAMPIN

AP AKORN STRIDES 600MG/VIAL N65421 001 May 22, 2008 May NEWA

RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

PROCTER AND GAMBLE 150MG

N20835 005 Apr 22, 2008 Apr NEWA

RISPERIDONE

INJECTABLE; INTRAMUSCULAR

RISPERDAL CONSTA

| | | | |
|-----|----------------|-------------|----------------------------------|
| >D> | JANSSEN PHARMA | 12.5MG/VIAL | N21346 004 Apr 12, 2007 Jun CAHN |
| >D> | | 25MG/VIAL | N21346 001 Oct 29, 2003 Jun CAHN |
| >D> | | 37.5MG/VIAL | N21346 002 Oct 29, 2003 Jun CAHN |
| >D> | + | 50MG/VIAL | N21346 003 Oct 29, 2003 Jun CAHN |
| >A> | ORTHO MCNEIL | 12.5MG/VIAL | N21346 004 Apr 12, 2007 Jun CAHN |
| >A> | | 25MG/VIAL | N21346 001 Oct 29, 2003 Jun CAHN |
| >A> | | 37.5MG/VIAL | N21346 002 Oct 29, 2003 Jun CAHN |
| >A> | + | 50MG/VIAL | N21346 003 Oct 29, 2003 Jun CAHN |

SOLUTION; ORAL

RISPERDAL

| | | | |
|-----|------------------|--------|----------------------------------|
| >D> | + JANSSEN PHARMA | 1MG/ML | N20588 001 Jun 10, 1996 Jun CAHN |
| >A> | + ORTHO MCNEIL | 1MG/ML | N20588 001 Jun 10, 1996 Jun CAHN |

TABLET; ORAL

RISPERDAL

| | | | |
|-----|-----------------|--------|----------------------------------|
| >D> | JANSSEN PHARMA | 0.25MG | N20272 008 May 10, 1999 Jun CFTG |
| >D> | | 0.5MG | N20272 007 Jan 27, 1999 Jun CFTG |
| >D> | + | 1MG | N20272 001 Dec 29, 1993 Jun CFTG |
| >D> | | 2MG | N20272 002 Dec 29, 1993 Jun CFTG |
| >D> | | 3MG | N20272 003 Dec 29, 1993 Jun CFTG |
| >D> | | 4MG | N20272 004 Dec 29, 1993 Jun CFTG |
| >D> | @ | 5MG | N20272 005 Dec 29, 1993 Jun CFTG |
| >A> | AB ORTHO MCNEIL | 0.25MG | N20272 008 May 10, 1999 Jun CFTG |
| >A> | AB | 0.5MG | N20272 007 Jan 27, 1999 Jun CFTG |
| >A> | AB + | 1MG | N20272 001 Dec 29, 1993 Jun CFTG |
| >A> | AB | 2MG | N20272 002 Dec 29, 1993 Jun CFTG |
| >A> | AB | 3MG | N20272 003 Dec 29, 1993 Jun CFTG |
| >A> | AB | 4MG | N20272 004 Dec 29, 1993 Jun CFTG |
| >A> | @ | 5MG | N20272 005 Dec 29, 1993 Jun CFTG |

RISPERIDONE

| | | | |
|-----|---------|--------|----------------------------------|
| >A> | AB TEVA | 0.25MG | N76228 001 Jun 30, 2008 Jun NEWA |
| >A> | AB | 0.5MG | N76228 002 Jun 30, 2008 Jun NEWA |
| >A> | AB | 1MG | N76228 003 Jun 30, 2008 Jun NEWA |
| >A> | AB | 2MG | N76228 004 Jun 30, 2008 Jun NEWA |
| >A> | AB | 3MG | N76228 005 Jun 30, 2008 Jun NEWA |
| >A> | AB | 4MG | N76228 006 Jun 30, 2008 Jun NEWA |

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERDAL

| | | | |
|-----|----------------|-------|----------------------------------|
| >D> | JANSSEN PHARMA | 0.5MG | N21444 001 Apr 02, 2003 Jun CAHN |
| >D> | + | 1MG | N21444 002 Apr 02, 2003 Jun CAHN |
| >D> | | 2MG | N21444 003 Apr 02, 2003 Jun CAHN |
| >D> | | 3MG | N21444 004 Dec 23, 2004 Jun CAHN |
| >D> | | 4MG | N21444 005 Dec 23, 2004 Jun CAHN |
| >A> | ORTHO MCNEIL | 0.5MG | N21444 001 Apr 02, 2003 Jun CAHN |
| >A> | + | 1MG | N21444 002 Apr 02, 2003 Jun CAHN |

TABLET, ORALLY DISINTEGRATING; ORAL
RISPERDAL

| | | | |
|-----|--------------|-----|----------------------------------|
| >A> | ORTHO MCNEIL | 2MG | N21444 003 Apr 02, 2003 Jun CAHN |
| >A> | | 3MG | N21444 004 Dec 23, 2004 Jun CAHN |
| >A> | | 4MG | N21444 005 Dec 23, 2004 Jun CAHN |

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

REQUIP

| | | | |
|----|-------------------|----------------|----------------------------------|
| AB | + GLAXOSMITHKLINE | EQ 0.25MG BASE | N20658 001 Sep 19, 1997 Apr CFTG |
| AB | | EQ 0.5MG BASE | N20658 002 Sep 19, 1997 Apr CFTG |
| AB | | EQ 1MG BASE | N20658 003 Sep 19, 1997 Apr CFTG |
| AB | | EQ 2MG BASE | N20658 004 Sep 19, 1997 Apr CFTG |
| AB | | EQ 3MG BASE | N20658 006 Jan 27, 1999 Apr CFTG |
| AB | | EQ 4MG BASE | N20658 007 Jan 27, 1999 Apr CFTG |
| AB | | EQ 5MG BASE | N20658 005 Sep 19, 1997 May CTEC |

ROPINIROLE HYDROCHLORIDE

| | | | |
|----|------------|----------------|----------------------------------|
| AB | COREPHARMA | EQ 0.25MG BASE | N78230 001 May 20, 2008 May NEWA |
| AB | | EQ 0.5MG BASE | N78230 002 May 20, 2008 May NEWA |
| AB | | EQ 1MG BASE | N78230 003 May 20, 2008 May NEWA |
| AB | | EQ 2MG BASE | N78230 004 May 20, 2008 May NEWA |
| AB | | EQ 3MG BASE | N78230 005 May 20, 2008 May NEWA |
| AB | | EQ 4MG BASE | N78230 006 May 20, 2008 May NEWA |
| AB | | EQ 5MG BASE | N78230 007 May 20, 2008 May NEWA |
| AB | MYLAN | EQ 0.25MG BASE | N78881 001 May 05, 2008 Apr NEWA |
| AB | | EQ 0.5MG BASE | N78881 002 May 05, 2008 Apr NEWA |
| AB | | EQ 1MG BASE | N78881 003 May 05, 2008 Apr NEWA |
| AB | | EQ 2MG BASE | N78881 004 May 05, 2008 Apr NEWA |
| AB | | EQ 3MG BASE | N78881 005 May 05, 2008 Apr NEWA |
| AB | | EQ 4MG BASE | N78881 006 May 05, 2008 Apr NEWA |
| AB | | EQ 5MG BASE | N78881 007 May 19, 2008 May NEWA |
| AB | PAR PHARM | EQ 0.25MG BASE | N78110 001 May 05, 2008 Apr NEWA |
| AB | | EQ 0.5MG BASE | N78110 002 May 05, 2008 Apr NEWA |
| AB | | EQ 1MG BASE | N78110 003 May 05, 2008 Apr NEWA |
| AB | | EQ 2MG BASE | N78110 004 May 05, 2008 Apr NEWA |
| AB | | EQ 3MG BASE | N78110 005 May 05, 2008 Apr NEWA |
| AB | | EQ 4MG BASE | N78110 006 May 05, 2008 Apr NEWA |
| AB | ROXANE | EQ 0.25MG BASE | N77852 001 May 05, 2008 Apr NEWA |
| AB | | EQ 0.5MG BASE | N77852 002 May 05, 2008 Apr NEWA |
| AB | | EQ 1MG BASE | N77852 003 May 05, 2008 Apr NEWA |
| AB | | EQ 2MG BASE | N77852 004 May 05, 2008 Apr NEWA |
| AB | | EQ 3MG BASE | N77852 005 May 05, 2008 Apr NEWA |
| AB | | EQ 4MG BASE | N77852 006 May 05, 2008 Apr NEWA |
| AB | | EQ 5MG BASE | N77852 007 May 19, 2008 May NEWA |
| AB | TEVA | EQ 0.25MG BASE | N77460 001 May 05, 2008 Apr NEWA |
| AB | | EQ 0.5MG BASE | N77460 002 May 05, 2008 Apr NEWA |
| AB | | EQ 1MG BASE | N77460 003 May 05, 2008 Apr NEWA |
| AB | | EQ 2MG BASE | N77460 004 May 05, 2008 Apr NEWA |
| AB | | EQ 3MG BASE | N77460 005 May 05, 2008 Apr NEWA |
| AB | | EQ 4MG BASE | N77460 006 May 05, 2008 Apr NEWA |
| AB | | EQ 5MG BASE | N77460 007 May 19, 2008 May NEWA |
| AB | WOCKHARDT | EQ 0.25MG BASE | N79050 001 May 29, 2008 May NEWA |
| AB | | EQ 0.5MG BASE | N79050 002 May 29, 2008 May NEWA |
| AB | | EQ 1MG BASE | N79050 003 May 29, 2008 May NEWA |
| AB | | EQ 2MG BASE | N79050 004 May 29, 2008 May NEWA |
| AB | | EQ 3MG BASE | N79050 005 May 29, 2008 May NEWA |

TABLET; ORALROPINIROLE HYDROCHLORIDE

| | | | | | | | | |
|-----|--------------------------------|-------------|--------|-----|---------|------|-----|------|
| AB | WOCKHARDT | EQ 4MG BASE | N79050 | 006 | May 29, | 2008 | May | NEWA |
| AB | | EQ 5MG BASE | N79050 | 007 | May 29, | 2008 | May | NEWA |
| >A> | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| >A> | REQUIP XL | | | | | | | |
| >A> | + SMITHKLINE BEECHAM | EQ 2MG BASE | N22008 | 001 | Jun 13, | 2008 | Jun | NEWA |
| >A> | | EQ 3MG BASE | N22008 | 002 | Jun 13, | 2008 | Jun | NEWA |
| >A> | | EQ 4MG BASE | N22008 | 003 | Jun 13, | 2008 | Jun | NEWA |
| >A> | | EQ 8MG BASE | N22008 | 004 | Jun 13, | 2008 | Jun | NEWA |

ROPIVACAINE HYDROCHLORIDE MONOHYDRATEINJECTABLE; INJECTIONNAROPIN

| | | | | | | | | |
|-----|--------------------|----------|--------|-----|---------|------|-----|------|
| >D> | ABRAXIS BIOSCIENCE | 2MG/ML | N20533 | 001 | Sep 24, | 1996 | Jun | CAHN |
| >A> | | 2MG/ML | N20533 | 001 | Sep 24, | 1996 | Jun | CAHN |
| >D> | | 5MG/ML | N20533 | 003 | Sep 24, | 1996 | Jun | CAHN |
| >A> | | 5MG/ML | N20533 | 003 | Sep 24, | 1996 | Jun | CAHN |
| >D> | | 7.5MG/ML | N20533 | 004 | Sep 24, | 1996 | Jun | CAHN |
| >A> | | 7.5MG/ML | N20533 | 004 | Sep 24, | 1996 | Jun | CAHN |
| >D> | + | 10MG/ML | N20533 | 005 | Sep 24, | 1996 | Jun | CAHN |
| >A> | + | 10MG/ML | N20533 | 005 | Sep 24, | 1996 | Jun | CAHN |

ROTIGOTINEFILM, EXTENDED RELEASE; TRANSDERMALNEUPRO

| | | | | | | | |
|-----------------------|----------|--------|-----|---------|------|-----|------|
| @ SCHWARZ BIOSCIENCES | 2MG/24HR | N21829 | 001 | May 09, | 2007 | Apr | DISC |
| @ | 4MG/24HR | N21829 | 002 | May 09, | 2007 | Apr | DISC |
| @ | 6MG/24HR | N21829 | 003 | May 09, | 2007 | Apr | DISC |

SERTACONAZOLE NITRATECREAM; TOPICALERTACZO

| | | | | | | | |
|-------------------|----|--------|-----|---------|------|-----|------|
| + ORTHONEUTROGENA | 2% | N21385 | 001 | Dec 10, | 2003 | Feb | CAHN |
|-------------------|----|--------|-----|---------|------|-----|------|

SERTRALINE HYDROCHLORIDETABLET; ORALSERTRALINE HYDROCHLORIDE

| | | | | | | | | |
|----|-----------------|---------------|--------|-----|---------|------|-----|------|
| AB | MATRIX LABS LTD | EQ 25MG BASE | N78626 | 001 | Jan 31, | 2008 | Jan | NEWA |
| AB | | EQ 50MG BASE | N78626 | 002 | Jan 31, | 2008 | Jan | NEWA |
| AB | | EQ 100MG BASE | N78626 | 003 | Jan 31, | 2008 | Jan | NEWA |

SILVER SULFADIAZINECREAM; TOPICALSSD

| | | | | | | | | |
|----|--------------|----|--------|-----|---------|------|-----|------|
| AB | DR REDDYS LA | 1% | N18578 | 001 | Feb 25, | 1982 | May | CAHN |
| BX | DR REDDYS LA | 1% | N18578 | 003 | Jul 11, | 1990 | May | CAHN |

SIMVASTATINTABLET; ORALSIMVASTATIN

| | | | | | | | | |
|----|-----------------|------|--------|-----|---------|------|-----|------|
| AB | ACCORD HLTHCARE | 10MG | N78155 | 002 | Feb 26, | 2008 | Feb | NEWA |
| AB | | 20MG | N78155 | 003 | Feb 26, | 2008 | Feb | NEWA |
| AB | | 40MG | N78155 | 004 | Feb 26, | 2008 | Feb | NEWA |
| AB | | 80MG | N78155 | 001 | Feb 26, | 2008 | Feb | NEWA |

| | | | |
|-------------------------------|---|-----------------------|----------------------------------|
| >D> | <u>SODIUM BICARBONATE; TARTARIC ACID</u> | | |
| >D> | GRANULE, EFFERVESCENT; ORAL | | |
| >D> | BAROS | | |
| >D> | LAFAYETTE PHARMS | 460MG/GM;420MG/GM | N18509 001 Aug 07, 1985 Jun DISC |
| >A> | @ | 460MG/GM;420MG/GM | N18509 001 Aug 07, 1985 Jun DISC |
| <u>SODIUM IODIDE, I-131</u> | | | |
| | CAPSULE; ORAL | | |
| | HICON | | |
| | DRAXIMAGE | 100uCi | N21305 004 Nov 18, 2004 Feb CTNA |
| >D> | IODOTOPE | | |
| >D> | + BRACCO | 1-130mCi | N10929 001 Jun DISC |
| >A> | @ | 1-130mCi | N10929 001 Jun DISC |
| | SOLUTION; ORAL | | |
| | HICON | | |
| | + DRAXIMAGE | 1-500mCi/0.5ML | N21305 003 Jan 24, 2003 Feb CTNA |
| | + | 1-250mCi/0.25ML | N21305 002 Jan 24, 2003 Feb CTNA |
| <u>SODIUM LACTATE</u> | | | |
| | INJECTABLE; INJECTION | | |
| | SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER | | |
| | @ HOSPIRA | 1.87GM/100ML | N18249 001 Apr DISC |
| <u>SOMATROPIN RECOMBINANT</u> | | | |
| | INJECTABLE; INJECTION | | |
| | ACCRETROPIN | | |
| | + CANGENE | 5MG/ML (5MG/ML) | N21538 001 Jan 23, 2008 Jan NEWA |
| | NORDITROPIN | | |
| >D> | BX NOVO NORDISK INC | 4MG/VIAL | N19721 001 May 08, 1995 Jun DISC |
| >A> | @ | 4MG/VIAL | N19721 001 May 08, 1995 Jun DISC |
| | BX | 5MG/1.5ML | N21148 001 Jun 20, 2000 Jan CTEC |
| >D> | | 8MG/VIAL | N19721 002 May 08, 1995 Jun DISC |
| >A> | @ | 8MG/VIAL | N19721 002 May 08, 1995 Jun DISC |
| | NORDITROPIN NORDIFLEX | | |
| | BX NOVO NORDISK INC | 5MG/1.5ML | N21148 004 Oct 01, 2004 Jan CTEC |
| | NUTROPIN AQ | | |
| | + GENENTECH | 5MG/2ML (2.5MG/ML) | N20522 003 Jan 03, 2008 Jan NEWA |
| | + | 10MG/2ML (5MG/ML) | N20522 001 Dec 29, 1995 Jan CPOT |
| | + | 20MG/2ML (10MG/ML) | N20522 004 Jan 03, 2008 Jan NEWA |
| | NUTROPIN AQ PEN | | |
| | + GENENTECH | 10MG/2ML (5MG/ML) | N20522 002 Apr 22, 2002 Jan CPOT |
| | OMNITROPE | | |
| | BX SANDOZ | 5MG/1.5ML | N21426 003 Jan 16, 2008 Jan NEWA |
| | SAIZEN | | |
| >D> | BX EMD SERONO | 4MG/VIAL | N19764 005 Jan 16, 2007 Jun DISC |
| >A> | @ | 4MG/VIAL | N19764 005 Jan 16, 2007 Jun DISC |
| | SEROSTIM | | |
| >D> | @ EMD SERONO | 8.8MG/VIAL | N20604 004 Sep 06, 2001 Jun CMFD |
| >A> | BX | 8.8MG/VIAL | N20604 004 Sep 06, 2001 Jun CMFD |
| | TEV-TROPIN | | |
| | BX + FERRING | 5MG/VIAL | N19774 002 Jan 04, 2002 Jan CPOT |
| >D> | INJECTABLE; SUBCUTANEOUS | | |
| >D> | SEROSTIM LQ | | |
| >D> | + EMD SERONO | 6MG/0.5ML (6MG/0.5ML) | N20604 005 Feb 11, 2005 Jun DISC |
| >A> | @ | 6MG/0.5ML (6MG/0.5ML) | N20604 005 Feb 11, 2005 Jun DISC |

>D> INJECTABLE; SUBCUTANEOUS
 >D> SEROSTIM LQ
 + EMD SERONO 6MG/0.5ML (6MG/0.5ML) N20604 005 Feb 11, 2005 Feb CMFD

SOTALOL HYDROCHLORIDE
 TABLET; ORAL
 SOTALOL HYDROCHLORIDE
 AB2 AMNEAL PHARM 80MG N77070 001 Nov 04, 2005 Feb CAHN
 AB2 120MG N77070 002 Nov 04, 2005 Feb CAHN
 AB2 160MG N77070 003 Nov 04, 2005 Feb CAHN
 @ MUTUAL PHARM 80MG N76576 001 Apr 08, 2004 Mar DISC
 @ 120MG N76576 002 Apr 08, 2004 Mar DISC
 @ 160MG N76576 003 Apr 08, 2004 Mar DISC

SPIRONOLACTONE
 TABLET; ORAL
 SPIRONOLACTONE
 @ MUTUAL PHARM 25MG N87265 001 Mar DISC

SULFAMETHOXAZOLE; TRIMETHOPRIM
 INJECTABLE; INJECTION
 SULFAMETHOXAZOLE AND TRIMETHOPRIM
 @ BAXTER HLTHCARE 80MG/ML;16MG/ML N70628 001 Dec 29, 1987 Mar DISC
 @ HOSPIRA 80MG/ML;16MG/ML N73199 001 Sep 11, 1992 Mar DISC
 + TEVA PARENTERAL 80MG/ML;16MG/ML N73303 001 Oct 31, 1991 Mar CRLD

SULFAPHENAZOLE
 SUSPENSION; ORAL
 SULFABID
 @ PHARM RES ASSOC 500MG/5ML N13093 001 May CAHN

SULFASALAZINE
 TABLET; ORAL
 SULFASALAZINE
 @ MUTUAL PHARM 500MG N89590 001 Oct 19, 1987 Mar DISC

TADALAFIL
 TABLET; ORAL
 CIALIS
 LILLY 2.5MG N21368 004 Jan 07, 2008 Jan NEWA

TAMOXIFEN CITRATE
 >D> SOLUTION; ORAL
 >D> SOLTAMOX
 >D> + ROSEMONT EQ 10MG BASE/5ML N21807 001 Oct 29, 2005 Jun DISC
 >A> @ EQ 10MG BASE/5ML N21807 001 Oct 29, 2005 Jun DISC

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT
 INJECTABLE; INJECTION
 >D> MACROTEC
 >D> BS BRACCO N/A N17833 001 Jun DISC
 >A> @ N/A N17833 001 Jun DISC

TECHNETIUM TC-99M GLUCEPTATE KIT

INJECTABLE; INJECTION
 TECHNESCAN GLUCEPTATE
 @ DRAXIMAGE N/A N18272 001 Jan 27, 1982 May DISC

TECHNETIUM TC-99M MEBROFENIN KIT

INJECTABLE; INJECTION
 CHOLETEC
 AP + BRACCO N/A N18963 001 Jan 21, 1987 Jan CFTG
 TECHNETIUM TC-99M MEBROFENIN
 AP CIS N/A N78242 001 Jan 29, 2008 Jan NEWA

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
 DRAXIMAGE MDP-25
 AP + DRAXIMAGE N/A N18035 002 Feb 27, 2004 Mar CTEC

TECHNETIUM TC-99M PYROPHOSPHATE KIT

INJECTABLE; INJECTION
 >D> PHOSPHOTEC
 >D> AP BRACCO N/A N17680 001 Jun DISC
 >A> @ N/A N17680 001 Jun DISC

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION
 CARDIOLITE
 >D> + BRISTOL MYERS SQUIBB N/A N19785 001 Dec 21, 1990 Jun CAHN
 >A> + LANTHEUS MEDCL N/A N19785 001 Dec 21, 1990 Jun CAHN
 MIRALUMA
 >D> @ BRISTOL MYERS SQUIBB N/A N19785 003 May 23, 1997 Jun CAHN
 >A> @ LANTHEUS MEDCL N/A N19785 003 May 23, 1997 Jun CAHN

TELBIVUDINE

TABLET; ORAL
 TYZEKA
 + NOVARTIS 600MG N22011 001 Oct 25, 2006 May CAHN

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
 TERAZOSIN HYDROCHLORIDE
 @ MYLAN TECHNOLOGIES EQ 1MG BASE N75384 001 Dec 01, 2000 Feb DISC
 @ EQ 2MG BASE N75384 002 Dec 01, 2000 Feb DISC
 @ EQ 5MG BASE N75384 003 Dec 01, 2000 Feb DISC
 @ EQ 10MG BASE N75384 004 Dec 01, 2000 Feb DISC

TERCONAZOLE

CREAM; VAGINAL
 TERAZOL 3
 >A> AB + ORTHO MCNEIL 0.8% N19964 001 Feb 21, 1991 Jun CAHN
 >D> AB + ORTHO MCNEIL PHARM 0.8% N19964 001 Feb 21, 1991 Jun CAHN
 TERAZOL 7
 >A> AB + ORTHO MCNEIL 0.4% N19579 001 Dec 31, 1987 Jun CAHN
 >D> AB + ORTHO MCNEIL PHARM 0.4% N19579 001 Dec 31, 1987 Jun CAHN

SUPPOSITORIY; VAGINAL

TERAZOL 3

| | | | | | |
|-----|----|---|----------------------|------|----------------------------------|
| >A> | AB | + | ORTHO MCNEIL JANSSEN | 80MG | N19641 001 May 24, 1988 Jun CAHN |
| >D> | AB | + | ORTHO MCNEIL PHARM | 80MG | N19641 001 May 24, 1988 Jun CAHN |

TESTOLACTONE

TABLET; ORAL

TESLAC

@ BRISTOL MYERS SQUIBB 50MG

N16118 001 Feb DISC

TESTOSTERONE

PELLET; IMPLANTATION

TESTOSTERONE

| | | | | |
|-----|--|--------|------|---------------------|
| >D> | | BARTOR | 75MG | N80911 001 Jun CRLD |
| >A> | | + | 75MG | N80911 001 Jun CRLD |

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HYDROCHLORIDE

@ PVT FORM 250MG
@ 500MGN62686 001 Jul 24, 1986 Apr CAHN
N62686 002 Jul 24, 1986 Apr CAHNTHALLOUS CHLORIDE, TL-201

INJECTABLE; INTRAVENOUS

THALLOUS CHLORIDE TL 201

AP MALLINCKRODT 2mCi/ML N77698 001 Nov 09, 2006 Apr CAHN

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

T-PHYL

@ PHARM RES ASSOC 200MG

N88253 001 Aug 17, 1983 May CAHN

UNIPHYL

AB PURDUE PHARM PRODS 400MG N87571 001 Sep 01, 1982 Feb CAHN
AB + 600MG N40086 001 Apr 15, 1996 Feb CAHNTHIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HYDROCHLORIDE

@ MUTUAL PHARM 50MG

N88370 001 Nov 18, 1983 Feb DISC

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

NAVANE

+ PFIZER EQ 5MG BASE/ML N16758 001 Jun DISC

>A> @ EQ 5MG BASE/ML N16758 001 Jun DISC

INJECTABLE; INJECTION

NAVANE

+ PFIZER EQ 10MG BASE/VIAL N16904 002 Jun DISC

>A> @ EQ 10MG BASE/VIAL N16904 002 Jun DISC

TIAGABINE HYDROCHLORIDE

TABLET; ORAL

GABITRIL

CEPHALON 2MG N20646 005 Apr 16, 1999 May CRLD

+ 4MG N20646 001 Sep 30, 1997 May CRLD

16MG N20646 003 Sep 30, 1997 May CRLD

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

| | | | |
|----|---------|---------------|----------------------------------|
| AT | FDC LTD | EQ 0.25% BASE | N77259 001 Apr 30, 2008 Apr NEWA |
| AT | | EQ 0.5% BASE | N77259 002 Apr 30, 2008 Apr NEWA |

TINZAPARIN SODIUM

INJECTABLE; INJECTION

INNOHEP

| | | | |
|-----|----------------|--------------|----------------------------------|
| >D> | + PHARMION | 20,000 IU/ML | N20484 001 Jul 14, 2000 Jun CAHN |
| >A> | + PHARMION LLC | 20,000 IU/ML | N20484 001 Jul 14, 2000 Jun CAHN |

TIPRANAVIR

| | | | |
|-----|------------------------|----------|----------------------------------|
| >A> | SOLUTION; ORAL | | |
| >A> | APTVIVUS | | |
| >A> | + BOEHRINGER INGELHEIM | 100MG/ML | N22292 001 Jun 23, 2008 Jun NEWA |

TIROFIBAN HYDROCHLORIDE

INJECTABLE; INJECTION

AGGRASTAT

@ MEDICURE

EQ 12.5MG BASE/50ML (EQ 0.25MG
BASE/ML)

N20912 001 May 14, 1998 Mar DISC

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN

| | | | |
|----|------------------------------------|--------------------|----------------------------------|
| AP | APP PHARMS | EQ 1.2GM BASE/VIAL | N50789 001 Jul 13, 2004 Feb CTEC |
| AP | + X GEN PHARMS | EQ 1.2GM BASE/VIAL | N65013 001 Aug 17, 2001 Feb CTEC |
| | TOBRAMYCIN SULFATE | | |
| AP | ABRAXIS PHARM | EQ 10MG BASE/ML | N65122 001 Nov 29, 2002 Mar CTNA |
| AP | + | EQ 40MG BASE/ML | N65122 002 Nov 29, 2002 Mar CTNA |
| AP | AKORN STRIDES | EQ 40MG BASE/ML | N65407 001 Mar 11, 2008 Feb NEWA |
| AP | APP PHARMS | EQ 1.2GM BASE/VIAL | N50789 001 Jul 13, 2004 Mar CTNA |
| AP | + X GEN PHARMS | EQ 1.2GM BASE/VIAL | N65013 001 Aug 17, 2001 Mar CTNA |
| | TOBRAMYCIN SULFATE (PHARMACY BULK) | | |
| AP | ABRAXIS PHARM | EQ 40MG BASE/ML | N65120 001 Nov 29, 2002 Mar CTNA |

TOLMETIN SODIUM

CAPSULE; ORAL

TOLECTIN DS

| | | | | | |
|-----|----|----------------------|---------------|------------|----------|
| >A> | AB | + ORTHO MCNEIL | EQ 400MG BASE | N18084 001 | Jun CAHN |
| >D> | AB | + ORTHO MCNEIL PHARM | EQ 400MG BASE | N18084 001 | Jun CAHN |

TABLET; ORAL

TOLECTIN

| | | | | | |
|-----|----|----------------------|---------------|------------|-----------------------|
| >A> | AB | ORTHO MCNEIL | EQ 200MG BASE | N17628 001 | Jun CAHN |
| >D> | AB | ORTHO MCNEIL PHARM | EQ 200MG BASE | N17628 001 | Jun CAHN |
| | | TOLECTIN 600 | | | |
| >A> | AB | + ORTHO MCNEIL | EQ 600MG BASE | N17628 002 | Mar 08, 1989 Jun CAHN |
| >D> | AB | + ORTHO MCNEIL PHARM | EQ 600MG BASE | N17628 002 | Mar 08, 1989 Jun CAHN |

TOPIRAMATE

CAPSULE; ORAL

TOPAMAX SPRINKLE

| | | | | |
|-----|---|--------------|------|----------------------------------|
| >A> | | ORTHO MCNEIL | 15MG | N20844 001 Oct 26, 1998 Jun CAHN |
| >A> | + | | 25MG | N20844 002 Oct 26, 1998 Jun CAHN |

CAPSULE; ORAL

TOPAMAX SPRINKLE

| | | | |
|-----|--------------------|------|----------------------------------|
| >A> | @ ORTHO MCNEIL | 50MG | N20844 003 Oct 26, 1998 Jun CAHN |
| >D> | ORTHO MCNEIL PHARM | 15MG | N20844 001 Oct 26, 1998 Jun CAHN |
| >D> | + | 25MG | N20844 002 Oct 26, 1998 Jun CAHN |
| >D> | @ | 50MG | N20844 003 Oct 26, 1998 Jun CAHN |

TABLET; ORAL

TOPAMAX

| | | | | |
|-----|---|--------------------|-------|----------------------------------|
| >A> | + | ORTHO MCNEIL | 25MG | N20505 004 Dec 24, 1996 Jun CAHN |
| >A> | | | 50MG | N20505 005 Dec 24, 1996 Jun CAHN |
| >A> | | | 100MG | N20505 001 Dec 24, 1996 Jun CAHN |
| >A> | | | 200MG | N20505 002 Dec 24, 1996 Jun CAHN |
| >A> | @ | | 300MG | N20505 003 Dec 24, 1996 Jun CAHN |
| >A> | @ | | 400MG | N20505 006 Dec 24, 1996 Jun CAHN |
| >D> | + | ORTHO MCNEIL PHARM | 25MG | N20505 004 Dec 24, 1996 Jun CAHN |
| >D> | | | 50MG | N20505 005 Dec 24, 1996 Jun CAHN |
| >D> | | | 100MG | N20505 001 Dec 24, 1996 Jun CAHN |
| >D> | | | 200MG | N20505 002 Dec 24, 1996 Jun CAHN |
| >D> | @ | | 300MG | N20505 003 Dec 24, 1996 Jun CAHN |
| >D> | @ | | 400MG | N20505 006 Dec 24, 1996 Jun CAHN |

TORSEMIDE

INJECTABLE; INJECTION

DEMADEX

| | | | | | |
|-----|----|---|-------|--------------------|----------------------------------|
| >D> | AP | + | ROCHE | 50MG/5ML (10MG/ML) | N20137 002 Aug 23, 1993 Jun DISC |
| >A> | | @ | | 50MG/5ML (10MG/ML) | N20137 002 Aug 23, 1993 Jun DISC |
| | AP | + | | 50MG/5ML (10MG/ML) | N20137 002 Aug 23, 1993 May CFTG |
| >A> | | @ | | 20MG/2ML (10MG/ML) | N20137 001 Aug 23, 1993 Jun DISC |

TORSEMIDE

| | | | | | |
|-----|----|---|--------------|--------------------|----------------------------------|
| >D> | AP | | BEDFORD LABS | 10MG/ML | N78007 001 Jun 11, 2008 Jun CRLD |
| >A> | AP | + | | 20MG/2ML (2MG/ML) | N78007 001 Jun 11, 2008 Jun CRLD |
| | AP | | | 10MG/ML | N78007 001 Jun 11, 2008 May NEWA |
| >A> | AP | + | | 50MG/5ML (10MG/ML) | N78007 002 Jun 11, 2008 Jun CRLD |

TABLET; ORAL

TORSEMIDE

| | | | | |
|----|--|----------------|-------|----------------------------------|
| AB | | SUN PHARM INDs | 5MG | N78478 001 Feb 26, 2008 Feb NEWA |
| AB | | | 10MG | N78478 002 Feb 26, 2008 Feb NEWA |
| AB | | | 20MG | N78478 003 Feb 26, 2008 Feb NEWA |
| AB | | | 100MG | N78478 004 Feb 26, 2008 Feb NEWA |

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

ULTRAM

| | | | | | |
|-----|----|---|--------------------|-------|----------------------------------|
| >A> | AB | + | ORTHO MCNEIL | 50MG | N20281 002 Mar 03, 1995 Jun CAHN |
| >A> | | @ | | 100MG | N20281 001 Mar 03, 1995 Jun CAHN |
| >D> | AB | + | ORTHO MCNEIL PHARM | 50MG | N20281 002 Mar 03, 1995 Jun CAHN |
| >D> | | @ | | 100MG | N20281 001 Mar 03, 1995 Jun CAHN |

TABLET, ORALLY DISINTEGRATING; ORAL

TRAMADOL HYDROCHLORIDE

| | | | |
|--|-----------|------|----------------------------------|
| | @ BIOVAIL | 50MG | N21693 001 May 05, 2005 May DISC |
|--|-----------|------|----------------------------------|

TRANDOLAPRIL

TABLET; ORAL

TRANDOLAPRIL

| | | | | | |
|-----|----|--|-------------------|-----|----------------------------------|
| >A> | AB | | GLENMARK GENERICS | 1MG | N78508 003 Jun 18, 2008 Jun NEWA |
| >A> | AB | | | 2MG | N78508 001 Jun 18, 2008 Jun NEWA |

TABLET; ORALTRANDOLAPRIL

| | | | | | | | |
|-----|----|-------------------|-----|------------|--------------|-----|------|
| >A> | AB | GLENMARK GENERICS | 4MG | N78508 002 | Jun 18, 2008 | Jun | NEWA |
| | AB | MYLAN | 1MG | N78346 001 | Apr 28, 2008 | Apr | NEWA |
| | AB | | 2MG | N78346 002 | Apr 28, 2008 | Apr | NEWA |
| | AB | | 4MG | N78346 003 | Apr 28, 2008 | Apr | NEWA |

TRIAMCINOLONE ACETONIDE

| | | | | | | | |
|-----|----|--|-----------------------|------------|--------------|-----|------|
| >A> | | INJECTABLE; INTRA-ARTICULAR, INTRAMUSCULAR, INTRAVITREAL | | | | | |
| >A> | | TRIVARIS | | | | | |
| >A> | + | ALLERGAN | 8MG/0.1ML (8MG/0.1ML) | N22220 001 | Jun 16, 2008 | Jun | NEWA |
| | | PASTE; DENTAL | | | | | |
| >D> | | KENALOG IN ORABASE | | | | | |
| >D> | AT | + APOTHECON | 0.1% | N12097 001 | | Jun | DISC |
| >A> | | @ | 0.1% | N12097 001 | | Jun | DISC |
| | | ORACORT | | | | | |
| >D> | AT | TARO | 0.1% | N70730 001 | Oct 01, 1986 | Jun | CRLD |
| >A> | AT | + | 0.1% | N70730 001 | Oct 01, 1986 | Jun | CRLD |
| >D> | | ORALONE | | | | | |
| >D> | AT | TARO | 0.1% | N71383 001 | Jul 06, 1987 | Jun | DISC |
| >A> | | @ | 0.1% | N71383 001 | Jul 06, 1987 | Jun | DISC |

TRIFLUOPERAZINE HYDROCHLORIDE

| | | | | | | | |
|-----|----|-------------------------------|-----------------|-----------------|--------------|-----|----------|
| >D> | | CONCENTRATE; ORAL | | | | | |
| >D> | | STELAZINE | | | | | |
| >D> | AA | + | GLAXOSMITHKLINE | EQ 10MG BASE/ML | N11552 006 | | Jun DISC |
| >A> | | @ | | EQ 10MG BASE/ML | N11552 006 | | Jun DISC |
| | | TABLET; ORAL | | | | | |
| >D> | | STELAZINE | | | | | |
| >D> | AB | GLAXOSMITHKLINE | EQ 1MG BASE | N11552 001 | | Jun | DISC |
| >A> | | @ | EQ 1MG BASE | N11552 001 | | Jun | DISC |
| >D> | AB | | EQ 2MG BASE | N11552 002 | | Jun | DISC |
| >A> | | @ | EQ 2MG BASE | N11552 002 | | Jun | DISC |
| >D> | AB | | EQ 5MG BASE | N11552 003 | | Jun | DISC |
| >A> | | @ | EQ 5MG BASE | N11552 003 | | Jun | DISC |
| >D> | AB | + | EQ 10MG BASE | N11552 004 | | Jun | DISC |
| >A> | | @ | EQ 10MG BASE | N11552 004 | | Jun | DISC |
| | | TRIFLUOPERAZINE HYDROCHLORIDE | | | | | |
| >D> | AB | MYLAN | EQ 10MG BASE | N40209 004 | Jul 07, 1997 | Jun | CRLD |
| >A> | AB | + | EQ 10MG BASE | N40209 004 | Jul 07, 1997 | Jun | CRLD |
| >D> | AB | SANDOZ | EQ 1MG BASE | N40153 001 | Oct 25, 1996 | Jun | DISC |
| >A> | | @ | EQ 1MG BASE | N40153 001 | Oct 25, 1996 | Jun | DISC |
| >D> | AB | | EQ 2MG BASE | N40153 002 | Oct 25, 1996 | Jun | DISC |
| >A> | | @ | EQ 2MG BASE | N40153 002 | Oct 25, 1996 | Jun | DISC |
| >D> | AB | | EQ 5MG BASE | N40153 003 | Oct 25, 1996 | Jun | DISC |
| >A> | | @ | EQ 5MG BASE | N40153 003 | Oct 25, 1996 | Jun | DISC |
| >D> | AB | | EQ 10MG BASE | N40153 004 | Oct 25, 1996 | Jun | DISC |
| >A> | | @ | EQ 10MG BASE | N40153 004 | Oct 25, 1996 | Jun | DISC |

TRIMETHOPRIMTABLET; ORAL

| | | | | | | | |
|-----|----|----------------|-------|------------|--|-----|------|
| >D> | | PROLOPRIM | | | | | |
| >D> | AB | MONARCH PHARMS | 100MG | N17943 001 | | Jun | DISC |
| >A> | | @ | 100MG | N17943 001 | | Jun | DISC |

TROLAMINE POLYPEPTIDE OLEATE CONDENSATE

SOLUTION/DROPS; OTIC

CERUMENEX

@ PHARM RES ASSOC

10%

N11340 002

May CAHN

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

AA MORTON GROVE

250MG/5ML

N70868 001 Jul 01, 1986 Feb CTNA

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOMYCIN HYDROCHLORIDE

| | | | | |
|-----|----|-------------|--------------------|----------------------------------|
| >A> | AP | GENERAMEDIX | EQ 500MG BASE/VIAL | N65401 001 Jun 30, 2008 Jun NEWA |
| >A> | AP | | EQ 1GM BASE/VIAL | N65401 002 Jun 30, 2008 Jun NEWA |

VARDENAFIL HYDROCHLORIDE

TABLET; ORAL

LEVITRA

BAYER HLTHCARE

2.5MG

N21400 003 Aug 19, 2003 Jan CAHN

5MG

N21400 001 Aug 19, 2003 Jan CAHN

10MG

N21400 002 Aug 19, 2003 Jan CAHN

+

20MG

N21400 004 Aug 19, 2003 Jan CAHN

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

@ HOSPIRA

4MG/VIAL

N75558 001 Sep 11, 2001 Apr DISC

VENLAFAKINE HYDROCHLORIDE

TABLET; ORAL

VENLAFAKINE HYDROCHLORIDE

| | | | | |
|-----|----|--------------------|----------------|----------------------------------|
| >A> | AB | CARACO | EQ 25MG BASE | N78627 001 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 37.5MG BASE | N78627 002 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 50MG BASE | N78627 003 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 75MG BASE | N78627 004 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 100MG BASE | N78627 005 Jun 13, 2008 Jun NEWA |
| >A> | AB | DR REDDYS LABS LTD | EQ 25MG BASE | N78301 001 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 37.5MG BASE | N78301 002 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 50MG BASE | N78301 003 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 75MG BASE | N78301 004 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 100MG BASE | N78301 005 Jun 13, 2008 Jun NEWA |
| >A> | AB | MYLAN | EQ 25MG BASE | N77166 001 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 37.5MG BASE | N77166 002 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 50MG BASE | N77166 003 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 75MG BASE | N77166 004 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 100MG BASE | N77166 005 Jun 13, 2008 Jun NEWA |
| >A> | AB | PLIVA HRVATSKA DOO | EQ 25MG BASE | N78517 001 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 37.5MG BASE | N78517 002 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 50MG BASE | N78517 003 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 75MG BASE | N78517 004 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 100MG BASE | N78517 005 Jun 13, 2008 Jun NEWA |
| >A> | AB | SANDOZ | EQ 25MG BASE | N77515 001 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 37.5MG BASE | N77515 002 Jun 13, 2008 Jun NEWA |
| >A> | AB | | EQ 50MG BASE | N77515 003 Jun 13, 2008 Jun NEWA |

TABLET; ORALVENLAFAXINE HYDROCHLORIDE

| | | | | | | | |
|-----|----|------------------|----------------|------------|--------------|-----|------|
| >A> | AB | SANDOZ | EQ 75MG BASE | N77515 004 | Jun 13, 2008 | Jun | NEWA |
| >A> | AB | | EQ 100MG BASE | N77515 005 | Jun 13, 2008 | Jun | NEWA |
| >A> | AB | ZYDUS PHARMS USA | EQ 25MG BASE | N77653 001 | Jun 13, 2008 | Jun | NEWA |
| >A> | AB | | EQ 37.5MG BASE | N77653 002 | Jun 13, 2008 | Jun | NEWA |
| >A> | AB | | EQ 50MG BASE | N77653 003 | Jun 13, 2008 | Jun | NEWA |
| >A> | AB | | EQ 75MG BASE | N77653 004 | Jun 13, 2008 | Jun | NEWA |
| >A> | AB | | EQ 100MG BASE | N77653 005 | Jun 13, 2008 | Jun | NEWA |

TABLET, EXTENDED RELEASE; ORALVENLAFAXINE HYDROCHLORIDE

| | | | | | | |
|---|----------------|----------------|------------|--------------|-----|------|
| | OSMOTICA PHARM | EQ 37.5MG BASE | N22104 001 | May 20, 2008 | May | NEWA |
| | | EQ 75MG BASE | N22104 002 | May 20, 2008 | May | NEWA |
| + | | EQ 150MG BASE | N22104 003 | May 20, 2008 | May | NEWA |
| | | EQ 225MG BASE | N22104 004 | May 20, 2008 | May | NEWA |

VINORELBINE TARTRATEINJECTABLE; INJECTIONVINORELBINE TARTRATE

| | | | | | | |
|----|--------------|-----------------|------------|--------------|-----|------|
| AP | EBEWE PHARMA | EQ 10MG BASE/ML | N78408 001 | Feb 13, 2008 | Jan | NEWA |
|----|--------------|-----------------|------------|--------------|-----|------|

WARFARIN POTASSIUMTABLET; ORALATHROMBIN-K

| | | | | | |
|---|-----------------|------|------------|-----|------|
| @ | PHARM RES ASSOC | 2MG | N11771 007 | May | CAHN |
| @ | | 5MG | N11771 004 | May | CAHN |
| @ | | 10MG | N11771 005 | May | CAHN |
| @ | | 25MG | N11771 006 | May | CAHN |

WARFARIN SODIUMTABLET; ORALATHROMBIN

| | | | | | |
|---|-----------------|------|------------|-----|------|
| @ | PHARM RES ASSOC | 5MG | N11771 003 | May | CAHN |
| @ | | 10MG | N11771 002 | May | CAHN |
| @ | | 25MG | N11771 001 | May | CAHN |

>D> ZALCITABINE>D> TABLET; ORAL>D> HIVID>D> ROCHE

0.375MG

N20199 001 Jun 19, 1992 Jun DISC

>A> @ 0.375MG N20199 001 Jun 19, 1992 Jun DISC

>D> + 0.75MG N20199 002 Jun 19, 1992 Jun DISC

>A> @ 0.75MG N20199 002 Jun 19, 1992 Jun DISC

ZALEPLONCAPSULE; ORALSONATA

| | | | | | | |
|----|-------------|------|------------|--------------|-----|------|
| AB | KING PHARMS | 5MG | N20859 001 | Aug 13, 1999 | May | CFTG |
| AB | + | 10MG | N20859 002 | Aug 13, 1999 | May | CFTG |

ZALEPLON

| | | | | | | |
|----|------------------|-----|------------|--------------|-----|------|
| AB | AUROBINDO PHARMA | 5MG | N78829 001 | Jun 06, 2008 | May | NEWA |
|----|------------------|-----|------------|--------------|-----|------|

AB 10MG N78829 002 Jun 06, 2008 May NEWA

| | | | | | | | |
|-----|----|-----------|-----|------------|--------------|-----|------|
| >A> | AB | CIPLA LTD | 5MG | N77505 001 | Jun 20, 2008 | Jun | NEWA |
|-----|----|-----------|-----|------------|--------------|-----|------|

AB 10MG N77505 002 Jun 20, 2008 Jun NEWA

| | | | | | | | |
|-----|----|----------|-----|------------|--------------|-----|------|
| >A> | AB | GENPHARM | 5MG | N77238 001 | Jun 06, 2008 | May | NEWA |
|-----|----|----------|-----|------------|--------------|-----|------|

AB 10MG N77238 002 Jun 06, 2008 May NEWA

CAPSULE; ORAL

ZALEPLON

| | | | |
|----|--------------|------|----------------------------------|
| AB | ROXANE | 5MG | N77237 001 Jun 06, 2008 May NEWA |
| AB | | 10MG | N77237 002 Jun 06, 2008 May NEWA |
| AB | SANDOZ | 5MG | N78095 001 Jun 06, 2008 May NEWA |
| AB | | 10MG | N78095 002 Jun 06, 2008 May NEWA |
| AB | TEVA PHARMS | 5MG | N77239 001 Jun 06, 2008 May NEWA |
| AB | | 10MG | N77239 002 Jun 06, 2008 May NEWA |
| AB | UNICHEM | 5MG | N78989 001 Jun 06, 2008 May NEWA |
| AB | | 10MG | N78989 002 Jun 06, 2008 May NEWA |
| AB | UPSHER SMITH | 5MG | N78706 001 Jun 06, 2008 May NEWA |
| AB | | 10MG | N78706 002 Jun 06, 2008 May NEWA |

ZIDOVUDINE

SYRUP; ORAL

ZIDOVUDINE

| | | | | |
|-----|----|------------------|----------|----------------------------------|
| >A> | AA | CIPLA LTD | 50MG/5ML | N77981 001 Jun 26, 2008 Jun NEWA |
| | | TABLET; ORAL | | |
| | | ZIDOVUDINE | | |
| AB | | HETERO DRUGS LTD | 300MG | N90092 001 Apr 25, 2008 Apr NEWA |
| AB | | MATRIX LABS LTD | 300MG | N78922 001 Feb 14, 2008 Jan NEWA |

ZILEUTON

TABLET; ORAL

ZYFLO

@ CRITICAL

600MG

N20471 003 Dec 09, 1996 Feb DISC

ZOLPIDEM TARTRATE

TABLET; ORAL

ZOLPIDEM TARTRATE

| | | | | |
|----|--|-------|------|----------------------------------|
| AB | | HIKMA | 5MG | N78129 001 Apr 30, 2008 Apr NEWA |
| AB | | | 10MG | N78129 002 Apr 30, 2008 Apr NEWA |

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

| | | | | |
|-----|----|--------|-------|----------------------------------|
| >D> | AB | ROXANE | 25MG | N77648 001 Dec 22, 2005 Jun DISC |
| >A> | | @ | 25MG | N77648 001 Dec 22, 2005 Jun DISC |
| >D> | AB | | 50MG | N77648 002 Dec 22, 2005 Jun DISC |
| >A> | | @ | 50MG | N77648 002 Dec 22, 2005 Jun DISC |
| >D> | AB | | 100MG | N77648 003 Dec 22, 2005 Jun DISC |
| >A> | | @ | 100MG | N77648 003 Dec 22, 2005 Jun DISC |

OTC DRUG PRODUCT LIST - 28TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

2-1

AVOBENZONE; ECAMSLIDE; OCTOCRYLENE; TITANIUM DIOXIDE

CREAM; TOPICAL
 ANTHELIOS 40
 + LOREAL USA 2%;3%;10%;5% N22009 001 Mar 31, 2008 Mar NEWA

CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE

TABLET, CHEWABLE; ORAL
 CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE
 PERRIGO R AND D 800MG;10MG;165MG N77355 001 Feb 06, 2008 Jan NEWA

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL
 CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY
 ACTAVIS MID ATLANTIC 5MG/5ML N90378 002 May 09, 2008 Apr NEWA
 APOTEX 5MG/5ML N90188 002 Apr 22, 2008 Apr NEWA
 PERRIGO R AND D 5MG/5ML N90254 002 Apr 09, 2008 Mar NEWA
 RANBAXY 5MG/5ML N90183 002 Apr 24, 2008 Apr NEWA
 TARO 5MG/5ML N90182 002 Apr 22, 2008 Apr NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

ACTAVIS MID ATLANTIC 5MG/5ML N90378 001 May 09, 2008 Apr NEWA
 APOTEX 5MG/5ML N90188 001 Apr 22, 2008 Apr NEWA
 PERRIGO R AND D 5MG/5ML N90254 001 Apr 09, 2008 Mar NEWA
 RANBAXY 5MG/5ML N90183 001 Apr 24, 2008 Apr NEWA
 TARO 5MG/5ML N90182 001 Apr 22, 2008 Apr NEWA

CHILDREN'S ZYRTEC ALLERGY

+ MCNEIL CONSUMER 5MG/5ML N22155 002 Nov 16, 2007 Mar CPOT
 + 1MG/ML N22155 002 Nov 16, 2007 Jan CAHN
 CHILDREN'S ZYRTEC HIVES RELIEF
 + MCNEIL CONSUMER 5MG/5ML N22155 001 Nov 16, 2007 Mar CPOT
 + 1MG/ML N22155 001 Nov 16, 2007 Jan CAHN

TABLET, CHEWABLE; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY
 SANDOZ 5MG N78692 001 Feb 14, 2008 Jan NEWA
 10MG N78692 002 Feb 14, 2008 Jan NEWA

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY
 CONTRACT PHARMA 5MG N76047 001 Dec 27, 2007 Apr CAHN
 10MG N76047 002 Dec 27, 2007 Apr CAHN
 DR REDDYS LABS LTD 5MG N78343 004 Jan 15, 2008 Jan NEWA
 10MG N78343 003 Jan 15, 2008 Jan NEWA

CETIRIZINE HYDROCHLORIDE HIVES

CONTRACT PHARMA 5MG N76047 003 Dec 27, 2007 Apr CAHN
 10MG N76047 004 Dec 27, 2007 Apr CAHN
 DR REDDYS LABS LTD 5MG N78343 001 Jan 15, 2008 Jan NEWA
 10MG N78343 002 Jan 15, 2008 Jan NEWA

ZYRTEC ALLERGY

MCNEIL CONSUMER 5MG N19835 003 Nov 16, 2007 Jan CAHN
 + 10MG N19835 004 Nov 16, 2007 Jan CAHN

ZYRTEC HIVES RELIEF

MCNEIL CONSUMER 5MG N19835 005 Nov 16, 2007 Jan CAHN
 + 10MG N19835 006 Nov 16, 2007 Jan CAHN

CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

| | | |
|------------------|-----------|----------------------------------|
| SANDOZ | 5MG;120MG | N77991 001 Mar 05, 2008 Feb NEWA |
| TEVA PHARMS | 5MG;120MG | N77170 001 Feb 25, 2008 Feb NEWA |
| ZYRTEC-D 12 HOUR | | |
| + MCNEIL | 5MG;120MG | N21150 002 Nov 09, 2007 Jan CAHN |

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET, CHEWABLE; ORAL

IMODIUM MULTI-SYMPTOM RELIEF

| | | |
|------------------------------|-----------|----------------------------------|
| + MCNEIL | 2MG;125MG | N20606 001 Jun 26, 1996 Apr CTNA |
| TABLET; ORAL | | |
| IMODIUM MULTI-SYMPTOM RELIEF | | |
| + MCNEIL CONS | 2MG;125MG | N21140 001 Nov 30, 2000 Apr CTNA |

LORATADINE

CAPSULE; ORAL

CLARITIN

| | | | |
|-----|-------------------|------|----------------------------------|
| >A> | + SCHERING PLOUGH | 10MG | N21952 001 Jun 16, 2008 Jun NEWA |
|-----|-------------------|------|----------------------------------|

MENTHOL; METHYL SALICYLATE

PATCH; TOPICAL

SALONPAS

| | | |
|-------------|--------|----------------------------------|
| + HISAMITSU | 3%;10% | N22029 001 Feb 20, 2008 Feb NEWA |
|-------------|--------|----------------------------------|

MINOXIDIL

SOLUTION; TOPICAL

MINOXIDIL (FOR WOMEN)

| | | |
|----------------|----|----------------------------------|
| HI TECH PHARMA | 2% | N74731 002 May 11, 2005 Mar NEWA |
|----------------|----|----------------------------------|

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICOTINE POLACRILEX

| | | |
|-----------------|-------------|----------------------------------|
| PERRIGO R AND D | EQ 2MG BASE | N78967 001 Apr 23, 2008 Apr NEWA |
| | EQ 4MG BASE | N78968 001 Apr 23, 2008 Apr NEWA |

POTASSIUM IODIDE

TABLET; ORAL

THYROSafe

| | | |
|---------|------|----------------------------------|
| + RECIP | 65MG | N76350 001 Sep 10, 2002 Jan CAHN |
|---------|------|----------------------------------|

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

CUMULATIVE SUPPLEMENT NUMBER 06 JUNE 2008

NO JUNE 2008 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

<http://www.fda.gov/orphan/designat/list.htm>

**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY
ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO JUNE 2008 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ADEFOVIR DIPIVOXIL - HEP SERA</u> | | | | | | |
| | 021449 001 | | | | NPP | Dec 19, 2010 |
| <u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u> | | | | | | |
| | 075710 001 | | | | PC | Aug 04, 2008 |
| <u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u> | | | | | | |
| | 075710 002 | | | | PC | Aug 04, 2008 |
| <u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u> | | | | | | |
| | 075710 003 | | | | PC | Aug 04, 2008 |
| <u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u> | | | | | | |
| | 075710 004 | | | | PC | Aug 04, 2008 |
| <u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u> | | | | | | |
| | 075710 005 | | | | PC | Aug 04, 2008 |
| <u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u> | | | | | | |
| | 076184 001 | | | | PC | Aug 04, 2008 |
| <u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKturna HCT</u> | | | | | | |
| 022107 001 | 5559111 | Apr 04, 2015 | DS DP U-3 | | NCE NC | Mar 05, 2012 Jan 18, 2011 |
| <u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKturna HCT</u> | | | | | | |
| 022107 002 | 5559111 | Apr 04, 2015 | DS DP U-3 | | NCE NC | Mar 05, 2012 Jan 18, 2011 |
| <u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKturna HCT</u> | | | | | | |
| 022107 003 | 5559111 | Apr 04, 2015 | DS DP U-3 | | NCE NC | Mar 05, 2012 Jan 18, 2011 |
| <u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKturna HCT</u> | | | | | | |
| 022107 004 | 5559111 | Apr 04, 2015 | DS DP U-3 | | NCE NC | Mar 05, 2012 Jan 18, 2011 |
| <u>ALOSETRON HYDROCHLORIDE - LOTRONEX</u> | | | | | | |
| | 021107 001 | | | | D-113 | Apr 01, 2011 |
| <u>ALOSETRON HYDROCHLORIDE - LOTRONEX</u> | | | | | | |
| | 021107 002 | | | | D-113 | Apr 01, 2011 |
| <u>ALVIMOPAN - ENTEREG</u> | | | | | | |
| 021775 001 | >A> 5250542 | Mar 29, 2011 | DS DP U-878 | | NCE | May 20, 2013 |
| | >A> 5434171 | Dec 08, 2013 | DS DP U-878 | | | |
| | >A> 6469030 | Nov 29, 2020 | U-879 | | | |
| <u>AMIFOSTINE - AMIFOSTINE</u> | | | | | | |
| | 077126 001 | | | | PC | Sep 23, 2008 |
| <u>AMLODIPINE BESYLATE - AMLODIPINE BESYLATE</u> | | | | | | |
| 022026 001 | >A> 6828339 | Nov 20, 2022 | DS | | | |
| <u>AMLODIPINE BESYLATE - AMLODIPINE BESYLATE</u> | | | | | | |
| 022026 002 | >A> 6828339 | Nov 20, 2022 | DS | | | |
| <u>AMLODIPINE BESYLATE - AMLODIPINE BESYLATE</u> | | | | | | |
| 022026 003 | >A> 6828339 | Nov 20, 2022 | DS | | | |
| <u>APREPITANT - EMEND</u> | | | | | | |
| 021549 001 | 5719147 | Apr 17, 2015 | DS DP U-853 | | | |
| | 7214692 | Sep 18, 2012 | U-853 | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>APREPITANT - EMEND</u> | | | | | | |
| 021549 002 | 7214692 | Sep 18, 2012 | U-853 | | | |
| <u>APREPITANT - EMEND</u> | | | | | | |
| 021549 003 | 7214692 | Sep 18, 2012 | U-853 | | | |
| <u>ARFORMOTEROL TARTRATE - BROVANA</u> | | | | | | |
| 021912 001 | 6040344 | Nov 12, 2016 | DS | | | |
| | 6472563 | Nov 09, 2021 | DS | | | |
| | 6720453 | Nov 09, 2021 | DS | | | |
| | 7145036 | Nov 09, 2021 | DS | | | |
| <u>ARGATROBAN - ARGATROBAN</u> | | | | | | |
| 020883 001 | | | | M-75 | | May 05, 2011 |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| 021436 001 | | | | D-115 | | May 06, 2011 |
| | | | | D-110 | | Oct 29, 2010 |
| | | | | I-559 | | May 06, 2011 |
| | | | | I-555 | | Feb 27, 2011 |
| | | | | PED | | Aug 27, 2011 |
| | | | | PED | | Apr 29, 2011 |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| 021436 002 | | | | D-115 | | May 06, 2011 |
| | | | | D-110 | | Oct 29, 2010 |
| | | | | I-559 | | May 06, 2011 |
| | | | | I-555 | | Feb 27, 2011 |
| | | | | PED | | Aug 27, 2011 |
| | | | | PED | | Apr 29, 2011 |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| 021436 003 | | | | D-115 | | May 06, 2011 |
| | | | | D-110 | | Oct 29, 2010 |
| | | | | I-559 | | May 06, 2011 |
| | | | | I-555 | | Feb 27, 2011 |
| | | | | PED | | Aug 27, 2011 |
| | | | | PED | | Apr 29, 2011 |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| 021436 004 | | | | D-115 | | May 06, 2011 |
| | | | | D-110 | | Oct 29, 2010 |
| | | | | I-559 | | May 06, 2011 |
| | | | | I-555 | | Feb 27, 2011 |
| | | | | PED | | Aug 27, 2011 |
| | | | | PED | | Apr 29, 2011 |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| 021436 005 | | | | D-115 | | May 06, 2011 |
| | | | | D-110 | | Oct 29, 2010 |
| | | | | I-559 | | May 06, 2011 |
| | | | | I-555 | | Feb 27, 2011 |
| | | | | PED | | Aug 27, 2011 |
| | | | | PED | | Apr 29, 2011 |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| 021436 006 | | | | D-115 | | May 06, 2011 |
| | | | | D-110 | | Oct 29, 2010 |
| | | | | I-559 | | May 06, 2011 |
| | | | | I-555 | | Feb 27, 2011 |
| | | | | PED | | Aug 27, 2011 |
| | | | | PED | | Apr 29, 2011 |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|--|------------|------------------------------|-----------------|--|--|-----------------------------------|
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| | 021713 001 | | | D-115 D-110 I-559 I-555 PED PED | May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011 | |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| | 021729 002 | | | D-115 D-110 I-559 I-555 PED PED | May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011 | |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| | 021729 003 | | | D-115 D-110 I-559 I-555 PED PED | May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011 | |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| | 021729 004 | | | D-115 D-110 I-559 I-555 PED PED | May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011 | |
| <u>ARIPIPRAZOLE - ABILIFY</u> | | | | | | |
| | 021729 005 | | | D-115 D-110 I-559 I-555 PED PED | May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011 | |
| <u>ATAZANAVIR SULFATE - REYATAZ</u> | | | | | | |
| | 021567 001 | | | NPP | Mar 25, 2011 | |
| <u>ATAZANAVIR SULFATE - REYATAZ</u> | | | | | | |
| | 021567 002 | | | NPP | Mar 25, 2011 | |
| <u>ATAZANAVIR SULFATE - REYATAZ</u> | | | | | | |
| | 021567 003 | | | NPP | Mar 25, 2011 | |
| <u>ATAZANAVIR SULFATE - REYATAZ</u> | | | | | | |
| | 021567 004 | | | NPP | Mar 25, 2011 | |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 001 | | | I-562 | May 07, 2011 | |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 002 | | | I-562 | May 07, 2011 | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 003 | | | | I-562 | May 07, 2011 |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 004 | | | | I-562 | May 07, 2011 |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 005 | | | | I-562 | May 07, 2011 |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 006 | | | | I-562 | May 07, 2011 |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 007 | | | | I-562 | May 07, 2011 |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | | |
| | 021411 008 | | | | I-562 | May 07, 2011 |
| <u>AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - ANTHELIOS 40</u> | | | | | | |
| | 022009 001 | | | | NP NC | Mar 31, 2011 Oct 05, 2009 |
| <u>BENDAMUSTINE HYDROCHLORIDE - TREANDA</u> | | | | | | |
| | 022249 001 | | | | NCE ODE | Mar 20, 2013 Mar 20, 2015 |
| <u>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX</u> | | | | | | |
| 021852 001 | RE39706 | Jun 09, 2015 | DS DP | | | |
| <u>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX SCALP</u> | | | | | | |
| 022185 001 | 6753013 | Jan 27, 2020 | DP U-88 | | NDF | May 09, 2011 |
| | 6753013 | Jan 27, 2020 | DP U-193 | | NC | Jan 09, 2009 |
| | 6787529 | Jan 27, 2020 | DP U-88 | | | |
| | 6787529 | Jan 27, 2020 | DP U-193 | | | |
| | RE39706 | Jun 09, 2015 | DS DP | | | |
| <u>BORTEZOMIB - VELCADE</u> | | | | | | |
| 021602 001 | >A> 6747150 | Oct 28, 2014 | DP | | >A> I-564 | Jun 20, 2011 |
| | 7119080 | Oct 28, 2014 | DP | | | |
| <u>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</u> | | | | | | |
| 021398 001 | 7030149 | Apr 19, 2022 | U-849 | | | |
| | 7320976 | Apr 19, 2022 | U-849 | | | |
| | 7323463 | Jan 19, 2023 | DP | | | |
| <u>BUDESONIDE - RHINOCORT</u> | | | | | | |
| 020746 001 | 6291445 | Apr 29, 2017 | | Y | | |
| | 6686346 | Apr 29, 2017 | DP U-557 | Y | | |
| | 6986904 | Apr 29, 2017 | DP U-699 | Y | | |
| <u>BUPROPION HYDROBROMIDE - APLENZIN</u> | | | | | | |
| 022108 001 | 7241805 | Jun 27, 2026 | DP | | | |
| <u>BUPROPION HYDROBROMIDE - APLENZIN</u> | | | | | | |
| 022108 002 | 7241805 | Jun 27, 2026 | DP | | | |
| <u>BUPROPION HYDROBROMIDE - APLENZIN</u> | | | | | | |
| 022108 003 | 7241805 | Jun 27, 2026 | DP | | | |
| <u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u> | | | | | | |
| 077284 001 | | | | | >A> PC | Nov 26, 2008 |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>BUPROPION HYDROCHLORIDE - WELLBUTRIN XL</u> | | | | | | |
| 021515 001 | 6143327 | Oct 30, 2018 | | Y | | |
| <u>CALCIPOTRIENE - CALCIPOTRIENE</u> | | | | | | |
| 078305 001 | | | | >A> PC | | Nov 02, 2008 |
| <u>CALCIPOTRIENE - DOVONEX</u> | | | | | | |
| 020554 001 | RE39706 | Jun 09, 2015 | DS DP | | | |
| <u>CALCIPOTRIENE - DOVONEX</u> | | | | | | |
| 020611 001 | RE39706 | Jun 09, 2015 | DS DP | | | |
| <u>CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE - ATACAND HCT</u> | | | | | | |
| 021093 003 | >A> 5196444 | Jun 04, 2012 | DS DP U-3 | | | |
| | >A> 5534534 | Jul 09, 2013 | DP | | | |
| | >A> 5705517 | Apr 18, 2011 | DS DP U-3 | | | |
| | >A> 5721263 | Feb 24, 2015 | DP U-3 | | | |
| | >A> 5958961 | Jun 06, 2014 | DP U-3 | | | |
| <u>CARVEDILOL - COREG</u> | | | | | | |
| 020297 001 | RE40000 | Jun 07, 2015 | | U-233 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL - COREG</u> | | | | | | |
| 020297 002 | RE40000 | Jun 07, 2015 | | U-233 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL - COREG</u> | | | | | | |
| 020297 003 | RE40000 | Jun 07, 2015 | | U-233 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL - COREG</u> | | | | | | |
| 020297 004 | RE40000 | Jun 07, 2015 | | U-233 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL PHOSPHATE - COREG CR</u> | | | | | | |
| 022012 001 | RE40000 | Jun 07, 2015 | | U-777 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL PHOSPHATE - COREG CR</u> | | | | | | |
| 022012 002 | RE40000 | Jun 07, 2015 | | U-777 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL PHOSPHATE - COREG CR</u> | | | | | | |
| 022012 003 | RE40000 | Jun 07, 2015 | | U-777 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |
| <u>CARVEDILOL PHOSPHATE - COREG CR</u> | | | | | | |
| 022012 004 | RE40000 | Jun 07, 2015 | | U-777 | | |
| | RE40000*PED | Dec 07, 2015 | | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>CASPOFUNGIN ACETATE - CANCIDAS</u> | | | | | | |
| 021227 001 | 5378804 | Mar 16, 2013 | DS | | | |
| | 5378804*PED | Sep 16, 2013 | | | | |
| | 5514650 | Jan 26, 2015 | | DP U-607 | | |
| | 5514650*PED | Jul 26, 2015 | | | | |
| | 5792746 | Mar 16, 2013 | DS DP | U-607 | | |
| | 5792746*PED | Sep 16, 2013 | | | | |
| | 5952300 | Mar 28, 2017 | DP | | | |
| | 5952300*PED | Sep 28, 2017 | | | | |
| | 6136783 | Mar 28, 2017 | | U-607 | | |
| | 6136783*PED | Sep 28, 2017 | | | | |
| <u>CASPOFUNGIN ACETATE - CANCIDAS</u> | | | | | | |
| 021227 002 | 5378804 | Mar 16, 2013 | DS | | | |
| | 5378804*PED | Sep 16, 2013 | | | | |
| | 5514650 | Jan 26, 2015 | | DP U-607 | | |
| | 5514650*PED | Jul 26, 2015 | | | | |
| | 5792746 | Mar 16, 2013 | DS DP | U-607 | | |
| | 5792746*PED | Sep 16, 2013 | | | | |
| | 5952300 | Mar 28, 2017 | DP | | | |
| | 5952300*PED | Sep 28, 2017 | | | | |
| | 6136783 | Mar 28, 2017 | | U-607 | | |
| | 6136783*PED | Sep 28, 2017 | | | | |
| <u>CICLESONIDE - ALVESCO</u> | | | | | | |
| 021658 002 | 5482934 | Jan 09, 2013 | DS DP | U-645 | | |
| | 5482934 | Jan 09, 2013 | DS DP | U-675 | | |
| | 5482934 | Jan 09, 2013 | DS DP | U-738 | | |
| | 5482934 | Jan 09, 2013 | DS DP | U-754 | | |
| | 5482934 | Jan 09, 2013 | DS DP | U-841 | | |
| | 5482934 | Jan 09, 2013 | DS DP | U-228 | | |
| | 5605674 | Feb 25, 2014 | DP | | | |
| | 5683677 | Nov 04, 2014 | DP | | | |
| | 5695743 | Jul 06, 2010 | DP | U-675 | | |
| | 5695743 | Jul 06, 2010 | DP | U-645 | | |
| | 5695743 | Jul 06, 2010 | DP | U-738 | | |
| | 5695743 | Jul 06, 2010 | DP | U-754 | | |
| | 5695743 | Jul 06, 2010 | DP | U-841 | | |
| | 5695743 | Jul 06, 2010 | DP | U-228 | | |
| | 5775321 | Jul 07, 2015 | DP | | | |
| | 6006745 | Dec 28, 2016 | DP | | | |
| | 6036942 | Apr 30, 2013 | DP | | | |
| | 6120752 | May 13, 2018 | DP | | | |
| | 6264923 | May 13, 2013 | DP | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>CICLESONIDE - ALVESCO</u> | | | | | | |
| 021658 003 | 5482934 | Jan 09, 2013 | DS DP U-645 | | | |
| | 5482934 | Jan 09, 2013 | DS DP U-675 | | | |
| | 5482934 | Jan 09, 2013 | DS DP U-738 | | | |
| | 5482934 | Jan 09, 2013 | DS DP U-754 | | | |
| | 5482934 | Jan 09, 2013 | DS DP U-841 | | | |
| | 5482934 | Jan 09, 2013 | DS DP U-228 | | | |
| | 5605674 | Feb 25, 2014 | DP | | | |
| | 5683677 | Nov 04, 2014 | DP | | | |
| | 5695743 | Jul 06, 2010 | DP U-675 | | | |
| | 5695743 | Jul 06, 2010 | DP U-645 | | | |
| | 5695743 | Jul 06, 2010 | DP U-738 | | | |
| | 5695743 | Jul 06, 2010 | DP U-754 | | | |
| | 5695743 | Jul 06, 2010 | DP U-841 | | | |
| | 5695743 | Jul 06, 2010 | DP U-228 | | | |
| | 5775321 | Jul 07, 2015 | DP | | | |
| | 6006745 | Dec 28, 2016 | DP | | | |
| | 6036942 | Apr 30, 2013 | DP | | | |
| | 6120752 | May 13, 2018 | DP | | | |
| | 6264923 | May 13, 2013 | DP | | | |
| <u>CLOBETASOL PROPIONATE - CLOBETASOL PROPIONATE</u> | | | | | | |
| 077763 001 | | | | | PC | Sep 16, 2008 |
| <u>CLOFARABINE - CLOLAR</u> | | | | | | |
| 021673 001 | 5661136 | Jan 14, 2018 | U-626 | | | |
| <u>CLOPIDOGREL BISULFATE - PLAVIX</u> | | | | | | |
| 020839 001 | 5576328 | Jan 31, 2014 | U-432 | Y | | |
| <u>CLOZAPINE - FAZACLO ODT</u> | | | | | | |
| 021590 001 | 6106861 | Dec 05, 2017 | DP | | | |
| <u>CLOZAPINE - FAZACLO ODT</u> | | | | | | |
| 021590 002 | 6106861 | Dec 05, 2017 | DP | | | |
| <u>CLOZAPINE - FAZACLO ODT</u> | | | | | | |
| 021590 003 | 6106861 | Dec 05, 2017 | DP | | | |
| <u>CLOZAPINE - FAZACLO ODT</u> | | | | | | |
| 021590 004 | 6106861 | Dec 05, 2017 | DP | | | |
| <u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u> | | | | | | |
| 021176 001 | 5919832 | Apr 29, 2014 | DS | | I-553 | Jan 18, 2011 |
| | 6066678 | Apr 29, 2014 | DS | U-323 | | |
| | 6433026 | Apr 29, 2014 | DS | | | |
| | 6784254 | Apr 29, 2014 | DS DP | | | |
| | 7229613 | Apr 17, 2022 | U-851 | | | |
| <u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u> | | | | | | |
| 021697 001 | 5723606 | Dec 15, 2019 | DS DP U-868 | | | |
| | 5723606 | Dec 15, 2019 | DS DP U-698 | | | |
| <u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u> | | | | | | |
| 021777 001 | >A> 7387793 | Feb 26, 2025 | DP | | | |

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| <u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u> | | | | | | |
| 021777 002 | >A> 7387793 | Feb 26, 2025 | DP | | | |
| <u>DAPTOMYCIN - CUBICIN</u> | | | | | | |
| 021572 002 | RE39071 | Jun 15, 2016 | DS DP U-728 | | | |
| <u>DARIFENACIN HYDROBROMIDE - ENABLEX</u> | | | | | | |
| 021513 001 | 5096890 | Mar 13, 2015 | DS DP U-631 | | | |
| <u>DARIFENACIN HYDROBROMIDE - ENABLEX</u> | | | | | | |
| 021513 002 | 5096890 | Mar 13, 2015 | DS DP U-631 | | | |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u> | | | | | | |
| 021976 002 | | | | NCE | | Jun 23, 2011 |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 001 | 6596746 | Jun 28, 2020 | DS DP U-780 | | | |
| | 6596746 | Jun 28, 2020 | DS DP U-748 | | | |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 002 | 6596746 | Jun 28, 2020 | DS DP U-780 | | | |
| | 6596746 | Jun 28, 2020 | DS DP U-748 | | | |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 003 | 6596746 | Jun 28, 2020 | DS DP U-780 | | | |
| | 6596746 | Jun 28, 2020 | DS DP U-748 | | | |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 004 | | | | D-109 | | Nov 06, 2010 |
| | | | | M-70 | | Nov 06, 2010 |
| | | | | NCE | | Jun 28, 2011 |
| | | | | ODE | | Jun 28, 2013 |
| <u>DEFERASIROX - EXJADE</u> | | | | | | |
| 021882 001 | >A> 6465504 | Apr 05, 2019 | DS DP | | | |
| <u>DEFERASIROX - EXJADE</u> | | | | | | |
| 021882 002 | >A> 6465504 | Apr 05, 2019 | DS DP | | | |
| <u>DEFERASIROX - EXJADE</u> | | | | | | |
| 021882 003 | >A> 6465504 | Apr 05, 2019 | DS DP | | | |
| <u>DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE</u> | | | | | | |
| 021795 001 | | | | NP | | May 08, 2011 |
| <u>DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE</u> | | | | | | |
| 021795 002 | | | | NP | | May 08, 2011 |
| <u>DESVENLAFAKINE SUCCINATE - PRISTIQ</u> | | | | | | |
| 021992 001 | 6673838 | Feb 11, 2022 | DS DP U-860 | | NCE | Mar 01, 2013 |
| | 7291347 | Feb 11, 2022 | DP | | | |
| <u>DESVENLAFAKINE SUCCINATE - PRISTIQ</u> | | | | | | |
| 021992 002 | 6673838 | Feb 11, 2022 | DS DP U-860 | | NCE | Mar 01, 2013 |
| | 7291347 | Feb 11, 2022 | DP | | | |
| <u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u> | | | | | | |
| 021802 001 | | | | M-74 | | Apr 11, 2009 |
| <u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u> | | | | | | |
| 021802 002 | | | | M-74 | | Apr 11, 2009 |

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| <u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u> | | | | | | |
| | 021802 003 | | | | M-74 | Apr 11, 2009 |
| <u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u> | | | | | | |
| | 021802 004 | | | | M-74 | Apr 11, 2009 |
| <u>DEXTROAMPHETAMINE SULFATE - DEXTROAMPHETAMINE SULFATE</u> | | | | | | |
| | 076814 001 | | | | PC | Aug 04, 2008 |
| <u>DIFLUPREDNATE - DUREZOL</u> | | | | | | |
| | 022212 001 | | | >A> NCE | | Jun 23, 2013 |
| <u>DIVALPROEX SODIUM - DEPAKOTE</u> | | | | | | |
| | 019680 001 | | | | M-34 PED | Mar 24, 2011 Sep 24, 2011 |
| <u>DIVALPROEX SODIUM - DEPAKOTE ER</u> | | | | | | |
| | 021168 001 | | | | M-34 PED | Mar 24, 2011 Sep 24, 2011 |
| <u>DIVALPROEX SODIUM - DEPAKOTE ER</u> | | | | | | |
| | 021168 002 | | | | M-34 PED | Mar 24, 2011 Sep 24, 2011 |
| <u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u> | | | | | | |
| | 020690 001 | 6372760 | Mar 31, 2019 | | Y | |
| <u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u> | | | | | | |
| | 020690 002 | 6372760 | Mar 31, 2019 | | Y | |
| <u>DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE - COSOPT</u> | | | | | | |
| | 020869 001 | 6248735 | Apr 17, 2011 | | Y | |
| | | 6316443 | Apr 17, 2011 | DP U-561 | Y | |
| <u>DOXORUBICIN HYDROCHLORIDE - DOXIL</u> | | | | | | |
| | 050718 002 | | | | >A> ODE | May 17, 2014 |
| <u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u> | | | | | | |
| | 021427 001 | >A> 5023269 | Jun 11, 2013 | DS DP U-882 | >A> I-566 | Jun 13, 2011 |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-839 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-799 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-797 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-796 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-795 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-605 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-398 | | |
| <u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u> | | | | | | |
| | 021427 002 | >A> 5023269 | Jun 11, 2013 | DS DP U-882 | >A> I-566 | Jun 13, 2011 |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-839 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-799 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-797 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-796 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-795 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-605 | | |
| | | >A> 5023269 | Jun 11, 2013 | DS DP U-398 | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u> | | | | | | |
| 021427 004 | >A> 5023269 | Jun 11, 2013 | DS DP U-882 | >A> | I-566 | Jun 13, 2011 |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-839 | | | |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-799 | | | |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-797 | | | |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-796 | | | |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-795 | | | |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-605 | | | |
| | >A> 5023269 | Jun 11, 2013 | DS DP U-398 | | | |
| <u>DUTASTERIDE - AVODART</u> | | | | | | |
| 021319 001 | | | | >A> | I-565 | Jun 19, 2011 |
| <u>EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA</u> | | | | | | |
| 021937 001 | 5914331 | Jul 02, 2017 | DS | | | |
| | 5914331*PED | Jan 02, 2018 | | | | |
| <u>ELETRIPTAN HYDROBROMIDE - RELPAX</u> | | | | | | |
| 021016 001 | 5545644 | Dec 26, 2016 | DS DP U-876 | | | |
| | 6110940 | Aug 29, 2017 | | | | |
| <u>ELETRIPTAN HYDROBROMIDE - RELPAX</u> | | | | | | |
| 021016 002 | 5545644 | Dec 26, 2016 | DS DP U-876 | | | |
| | 6110940 | Aug 29, 2017 | | | | |
| <u>EMTRICITABINE - EMTRIVA</u> | | | | | | |
| 021500 001 | 5914331 | Jul 02, 2017 | DS | | | |
| | 5914331*PED | Jan 02, 2018 | | | | |
| <u>EMTRICITABINE - EMTRIVA</u> | | | | | | |
| 021896 001 | 5914331 | Jul 02, 2017 | DS | | | |
| | 5914331*PED | Jan 02, 2018 | | | | |
| <u>EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - TRUVADA</u> | | | | | | |
| 021752 001 | 5914331 | Jul 02, 2017 | DS DP U-248 | | | |
| | 5914331*PED | Jan 02, 2018 | DS | | | |
| <u>ENFUVIRTIDE - FUZEON</u> | | | | | | |
| 021481 001 | 6133418 | Nov 17, 2014 | DS DP | | | |
| <u>ENTECAVIR - BARACLUDE</u> | | | | | | |
| 021797 001 | 5206244 | Feb 21, 2015 | DS | | | |
| <u>ENTECAVIR - BARACLUDE</u> | | | | | | |
| 021797 002 | 5206244 | Feb 21, 2015 | DS | | | |
| <u>ENTECAVIR - BARACLUDE</u> | | | | | | |
| 021798 001 | 5206244 | Feb 21, 2015 | DS | | | |
| <u>EPLERENONE - INSPRA</u> | | | | | | |
| 021437 001 | | | | M-72 | Jan 31, 2011 | |
| | | | | PED | Jul 31, 2011 | |
| <u>EPLERENONE - INSPRA</u> | | | | | | |
| 021437 002 | | | | M-72 | Jan 31, 2011 | |
| | | | | PED | Jul 31, 2011 | |

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| <u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u> | | | | | | |
| 021743 001 | 5747498 | Nov 08, 2018 | DS DP U-659 | | | |
| | 6900221 | Nov 09, 2020 | DS DP U-875 | | | |
| | 6900221 | Nov 09, 2020 | DS DP U-659 | | | |
| | 7087613 | Nov 09, 2020 | | U-659 | | |
| <u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u> | | | | | | |
| 021743 002 | 5747498 | Nov 08, 2018 | DS DP U-659 | | | |
| | 6900221 | Nov 09, 2020 | DS DP U-875 | | | |
| | 6900221 | Nov 09, 2020 | DS DP U-659 | | | |
| | 7087613 | Nov 09, 2020 | | U-659 | | |
| <u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u> | | | | | | |
| 021743 003 | 5747498 | Nov 08, 2018 | DS DP U-659 | | | |
| | 6900221 | Nov 09, 2020 | DS DP U-875 | | | |
| | 6900221 | Nov 09, 2020 | DS DP U-659 | | | |
| | 7087613 | Nov 09, 2020 | | U-659 | | |
| <u>ERTAPENEM SODIUM - INVANZ</u> | | | | | | |
| 021337 001 | 7342005 | Feb 02, 2013 | | DP | | |
| | 7342005*PED | Aug 02, 2013 | | | | |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021323 001 | 6916941 | Aug 12, 2022 | DS DP | | | |
| | 6916941*PED | Feb 12, 2023 | DS DP | | | |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021323 002 | 6916941 | Aug 12, 2022 | DS DP | | | |
| | 6916941*PED | Feb 12, 2023 | DS DP | | | |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021323 003 | 6916941 | Aug 12, 2022 | DS DP | | | |
| | 6916941*PED | Feb 12, 2023 | DS DP | | | |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | |
| 022101 001 | 5690960 | Nov 25, 2014 | | DP U-858 | I-504 | Oct 11, 2009 |
| | 5690960*PED | May 25, 2015 | | | NPP | Feb 27, 2011 |
| | 5714504 | Feb 03, 2015 | | DP U-858 | | |
| | 5714504*PED | Aug 03, 2015 | | | | |
| | 5877192 | May 27, 2014 | | U-858 | | |
| | 5877192*PED | Nov 27, 2014 | | | | |
| | 5900424 | May 04, 2016 | DS | U-858 | | |
| | 5900424*PED | Nov 04, 2016 | | | | |
| | 6369085 | May 25, 2018 | DS DP | U-858 | | |
| | 6369085*PED | Nov 25, 2018 | | | | |
| | 6428810 | Nov 03, 2019 | | DP U-858 | | |
| | 6428810*PED | May 03, 2020 | | | | |
| | 6875872 | May 27, 2014 | DS | | | |
| | 6875872*PED | Nov 27, 2014 | | | | |
| <u>ESTRADIOL; NORGESTIMATE - PREFEST</u> | | | | | | |
| 021040 001 | 7320970 | Mar 30, 2020 | | DP U-844 | | |
| <u>ESZOPICLONE - LUNESTA</u> | | | | | | |
| 021476 001 | >A> 7381724 | Jan 16, 2012 | DS DP | U-629 | | |

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| <u>ESZOPICLONE - LUNESTA</u> | | | | | | |
| 021476 002 | >A> 7381724 | Jan 16, 2012 | DS DP U-629 | | | |
| <u>ESZOPICLONE - LUNESTA</u> | | | | | | |
| 021476 003 | >A> 7381724 | Jan 16, 2012 | DS DP U-629 | | | |
| <u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u> | | | | | | |
| 021840 001 | 7320969 | Jan 30, 2024 | U-828 | | | |
| <u>ETRAVIRINE - INTELENCE</u> | | | | | | |
| 022187 001 | | | | NCE | | Jan 18, 2013 |
| <u>EXENATIDE SYNTHETIC - BYETTA</u> | | | | | | |
| 021773 001 | 5424286 | Dec 01, 2016 | U-653 | | | |
| <u>EZETIMIBE - ZETIA</u> | | | | | | |
| 021445 001 | 5846966 | Sep 21, 2013 | U-474 | | I-493 | May 23, 2009 |
| | 5846966 | Sep 21, 2013 | U-473 | >A> M-54 | Jun 05, 2011 | |
| | 5846966*PED | Mar 21, 2014 | | >A> PED | Dec 05, 2011 | |
| | 7030106 | Jan 25, 2022 | DP | PED | Nov 23, 2009 | |
| | 7030106*PED | Jul 25, 2022 | | | | |
| | RE37721 | Oct 25, 2016 | DS DP U-473 | | | |
| | RE37721*PED | Apr 25, 2017 | | | | |
| <u>EZETIMIBE; SIMVASTATIN - VYTORIN</u> | | | | | | |
| 021687 001 | >A> 5846966 | Sep 21, 2013 | DP U-593 | | M-60 | Oct 03, 2009 |
| | >A> 5846966 | Sep 21, 2013 | DP U-473 | | M-58 | Mar 16, 2009 |
| | 5846966*PED | Mar 21, 2014 | | >A> M-54 | Jun 05, 2011 | |
| | 7229982 | Dec 11, 2023 | DP U-592 | >A> PED | Dec 05, 2011 | |
| | 7229982*PED | Jun 11, 2024 | | PED | Apr 03, 2010 | |
| | RE37721 | Oct 25, 2016 | DS DP U-473 | | PED | Sep 16, 2009 |
| | RE37721*PED | Apr 25, 2017 | | | | |
| <u>EZETIMIBE; SIMVASTATIN - VYTORIN</u> | | | | | | |
| 021687 002 | >A> 5846966 | Sep 21, 2013 | DP U-593 | | M-60 | Oct 03, 2009 |
| | >A> 5846966 | Sep 21, 2013 | DP U-473 | | M-58 | Mar 16, 2009 |
| | 5846966*PED | Mar 21, 2014 | | >A> M-54 | Jun 05, 2011 | |
| | 7229982 | Dec 11, 2023 | DP U-592 | >A> PED | Dec 05, 2011 | |
| | 7229982*PED | Jun 11, 2024 | | PED | Apr 03, 2010 | |
| | RE37721 | Oct 25, 2016 | DS DP U-473 | | PED | Sep 16, 2009 |
| | RE37721*PED | Apr 25, 2017 | | | | |
| <u>EZETIMIBE; SIMVASTATIN - VYTORIN</u> | | | | | | |
| 021687 003 | >A> 5846966 | Sep 21, 2013 | DP U-593 | | M-60 | Oct 03, 2009 |
| | >A> 5846966 | Sep 21, 2013 | DP U-473 | | M-58 | Mar 16, 2009 |
| | 5846966*PED | Mar 21, 2014 | | >A> M-54 | Jun 05, 2011 | |
| | 7229982 | Dec 11, 2023 | DP U-592 | PED | Apr 03, 2010 | |
| | 7229982*PED | Jun 11, 2024 | | PED | Sep 16, 2009 | |
| | RE37721 | Oct 25, 2016 | DS DP U-473 | | PED | Dec 05, 2008 |
| | RE37721*PED | Apr 25, 2017 | | | | |

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| <u>EZETIMIBE; SIMVASTATIN - VYTORIN</u> | | | | | | |
| 021687 004 | >A> 5846966 | Sep 21, 2013 | DP U-593 | | M-60 | Oct 03, 2009 |
| | >A> 5846966 | Sep 21, 2013 | DP U-473 | | M-58 | Mar 16, 2009 |
| | 5846966*PED | Mar 21, 2014 | | | >A> M-54 | Jun 05, 2011 |
| | 7229982 | Dec 11, 2023 | DP U-592 | | >A> PED | Dec 05, 2011 |
| | 7229982*PED | Jun 11, 2024 | | | PED | Apr 03, 2010 |
| | RE37721 | Oct 25, 2016 | DS DP U-473 | | PED | Sep 16, 2009 |
| | RE37721*PED | Apr 25, 2017 | | | | |
| <u>FAMOTIDINE - PEPCID AC</u> | | | | | | |
| 020801 001 | 5075114 | Oct 23, 2010 | | | | |
| | 5075114*PED | Nov 23, 2010 | | | | |
| | 5667794 | May 02, 2015 | | | Y | |
| <u>FAMOTIDINE - PEPCID AC</u> | | | | | | |
| 020801 002 | 5075114 | May 23, 2010 | DP | | | |
| | 5075114*PED | Nov 23, 2010 | | | | |
| | 6814978 | Aug 26, 2021 | DP | | | |
| | 6814978*PED | Feb 26, 2022 | | | | |
| <u>FENOFIBRATE - TRICOR</u> | | | | | | |
| 021656 001 | 7320802 | Feb 21, 2023 | | U-847 | | |
| <u>FENOFIBRATE - TRICOR</u> | | | | | | |
| 021656 002 | 7320802 | Feb 21, 2023 | | U-847 | | |
| <u>FENTANYL CITRATE - FENTORA</u> | | | | | | |
| 021947 006 | 6200604 | Mar 26, 2019 | | U-767 | | |
| | 6974590 | Mar 26, 2019 | | U-767 | | |
| <u>FEXOFENADINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE</u> | | | | | | |
| 077081 002 | | | | | PC | Oct 21, 2008 |
| <u>FEXOFENADINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE</u> | | | | | | |
| 077081 003 | | | | | PC | Oct 21, 2008 |
| <u>FLUOCINONIDE - VANOS</u> | | | | | | |
| 021758 001 | 7220424 | Jan 07, 2023 | | U-861 | | |
| <u>FLUOXETINE HYDROCHLORIDE - FLUOXETINE HYDROCHLORIDE</u> | | | | | | |
| 076287 001 | | | | | PC | Nov 17, 2008 |
| <u>FLUOXETINE HYDROCHLORIDE - FLUOXETINE HYDROCHLORIDE</u> | | | | | | |
| 076287 002 | | | | | PC | Nov 17, 2008 |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 002 | 5945416 | Mar 24, 2017 | DS DP | | Y | |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 003 | 5945416 | Mar 24, 2017 | DS DP | | Y | |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 004 | 5945416 | Mar 24, 2017 | DS DP | | Y | |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 005 | 5945416 | Mar 24, 2017 | DS DP | | Y | |
| <u>FLUTICASONE PROPIONATE - FLOVENT HFA</u> | | | | | | |
| 021433 001 | 5658549 | Aug 19, 2014 | | DP U-710 | | |

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|--|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE - FLOVENT HFA</u> | | | | | | |
| 021433 002 | 5658549 | Aug 19, 2014 | DP | U-710 | | |
| <u>FLUTICASONE PROPIONATE - FLOVENT HFA</u> | | | | | | |
| 021433 003 | 5658549 | Aug 19, 2014 | DP | U-710 | | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u> | | | | | | |
| 021077 001 | RE40045 | Sep 07, 2010 | DP | | I-558 | Apr 30, 2011 |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u> | | | | | | |
| 021077 002 | 4992474 | Feb 12, 2008 | DS DP | U-872 | I-558 | Apr 30, 2011 |
| | 4992474 | Feb 12, 2008 | DS DP | U-211 | | |
| | 5225445 | Feb 12, 2008 | | U-872 | | |
| | 5225445 | Feb 12, 2008 | | U-211 | | |
| | RE40045 | Sep 07, 2010 | DP | | | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u> | | | | | | |
| 021077 003 | RE40045 | Sep 07, 2010 | DP | | I-558 | Apr 30, 2011 |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u> | | | | | | |
| 021254 001 | RE40045 | Sep 07, 2010 | DP | | | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u> | | | | | | |
| 021254 002 | RE40045 | Sep 07, 2010 | DP | | | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u> | | | | | | |
| 021254 003 | RE40045 | Sep 07, 2010 | DP | | | |
| <u>FLUVOXAMINE MALEATE - LUVOX CR</u> | | | | | | |
| 022033 001 | | | | | NDF | Feb 28, 2011 |
| <u>FLUVOXAMINE MALEATE - LUVOX CR</u> | | | | | | |
| 022033 002 | | | | | NDF | Feb 28, 2011 |
| <u>FORMOTEROL FUMARATE - PERFOROMIST</u> | | | | | | |
| 022007 001 | 7348362 | Jun 22, 2021 | DP | | | |
| <u>FOSAPREPITANT DIMEGLUMINE - EMEND</u> | | | | | | |
| 022023 001 | 5512570 | Mar 04, 2014 | | U-850 | | |
| | 5538982 | Jul 23, 2013 | | U-850 | | |
| | 5691336 | Mar 04, 2014 | DS DP | | | |
| | 5716942 | Feb 10, 2015 | | U-850 | | |
| | 7214692 | Sep 18, 2012 | | U-850 | | |
| <u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u> | | | | | | |
| 021357 001 | 4916246 | Apr 10, 2012 | DS | | | |
| <u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u> | | | | | | |
| 021357 002 | 4916246 | Apr 10, 2012 | DS | | | |
| <u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u> | | | | | | |
| 021357 003 | 4916246 | Apr 10, 2012 | DS | | | |
| <u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u> | | | | | | |
| 021357 004 | 4916246 | Apr 10, 2012 | DS | | | |
| <u>GADOBENATE DIMEGLUMINE - MULTIHANCE MULTIPACK</u> | | | | | | |
| 021358 001 | 4916246 | Apr 10, 2012 | DS | | | |

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|--|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>GADOBENATE DIMEGLUMINE - MULTIHANCE MULTIPACK</u> | | | | | | |
| 021358 002 | 4916246 | Apr 10, 2012 | DS | | | |
| <u>GEFITINIB - IRESSA</u> | | | | | | |
| 021399 001 | >A> 5770599 | May 05, 2017 | DS DP U-881 | | | |
| <u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u> | | | | | | |
| 021700 001 | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u> | | | | | | |
| 021700 002 | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u> | | | | | | |
| 021700 003 | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u> | | | | | | |
| 021700 004 | >A> 5002953 | Sep 17, 2011 | DS DP U-840 | | | |
| | >A> 5002953*PED | Mar 17, 2012 | | | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u> | | | | | | |
| 021700 005 | >A> 5002953 | Sep 17, 2011 | DS DP U-840 | | | |
| | >A> 5002953*PED | Mar 17, 2012 | | | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>GLYCOPYRROLATE - ROBINUL</u> | | | | | | |
| 012827 001 | >A> 7091236 | Aug 20, 2023 | U-877 | | | |
| <u>GLYCOPYRROLATE - ROBINUL FORTE</u> | | | | | | |
| 012827 002 | >A> 7091236 | Aug 20, 2023 | U-877 | | | |
| <u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE</u> | | | | | | |
| 077177 001 | | | | PC | | Jun 28, 2008 |
| <u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE</u> | | | | | | |
| 077165 001 | | | | PC | | Jun 28, 2008 |
| <u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u> | | | | | | |
| 020387 001 | 5608075 | Mar 04, 2014 | | Y | | |
| <u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u> | | | | | | |
| 020387 002 | 5608075 | Mar 04, 2014 | | Y | | |
| <u>HYDROCORTISONE BUTYRATE - LOCOID</u> | | | | | | |
| 022076 001 | >A> 7378405 | Dec 19, 2026 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u> | | | | | | |
| 019891 001 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u> | | | | | | |
| 019892 001 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u> | | | | | | |
| 019892 002 | >A> 6589960 | Nov 09, 2020 | DP | | | |

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|--|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u> | | | | | | |
| 019892 003 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID-HP</u> | | | | | | |
| 019034 001 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID-HP</u> | | | | | | |
| 019034 002 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - PALLADONE</u> | | | | | | |
| 021044 001 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - PALLADONE</u> | | | | | | |
| 021044 002 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - PALLADONE</u> | | | | | | |
| 021044 003 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>HYDROMORPHONE HYDROCHLORIDE - PALLADONE</u> | | | | | | |
| 021044 004 | >A> 6589960 | Nov 09, 2020 | DP | | | |
| <u>INSULIN ASPART RECOMBINANT - NOVOLOG</u> | | | | | | |
| 020986 001 | | | | | D-112 | Mar 14, 2011 |
| <u>INSULIN GLULISINE RECOMBINANT - APIDRA</u> | | | | | | |
| 021629 002 | >A> 6221633 | Jun 18, 2018 | DS DP U-471 | | | |
| <u>LAMIVUDINE - EPIVIR</u> | | | | | | |
| 020564 001 | 5047407 | Nov 17, 2009 | DS DP U-257 | | | |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 020406 001 | >A> 4628098 | May 10, 2009 | | | | |
| | >A> 4628098*PED | Nov 10, 2009 | | | | |
| | >A> 5013743 | Feb 12, 2010 | | U-452 | | |
| | >A> 5013743*PED | Aug 12, 2010 | | | | |
| | >A> 5026560 | Jun 25, 2008 | | | | |
| | >A> 5026560*PED | Dec 25, 2008 | | | | |
| | >A> 5045321 | Sep 03, 2008 | | | | |
| | >A> 5045321*PED | Mar 03, 2009 | | | | |
| | >A> 5093132 | Sep 03, 2008 | | | | |
| | >A> 5093132*PED | Mar 03, 2009 | | | | |
| | >A> 5433959 | Sep 03, 2008 | | | | |
| | >A> 5433959*PED | Mar 03, 2009 | | | | |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 020406 002 | >A> 4628098 | May 10, 2009 | | | | |
| | >A> 4628098*PED | Nov 10, 2009 | | | | |
| | >A> 5013743 | Feb 12, 2010 | | U-452 | | |
| | >A> 5013743*PED | Aug 12, 2010 | | | | |
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| | >A> 5433959 | Sep 03, 2008 | | | | |
| | >A> 5433959*PED | Mar 03, 2009 | | | | |

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| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 021281 001 | >A> 4628098 | May 10, 2009 | | | | |
| | >A> 4628098*PED | Nov 10, 2009 | | | | |
| | >A> 5013743 | Feb 12, 2010 | U-452 | | | |
| | >A> 5013743*PED | Aug 12, 2010 | | | | |
| | >A> 5026560 | Jun 25, 2008 | | | | |
| | >A> 5026560*PED | Dec 25, 2008 | | | | |
| | >A> 5045321 | Sep 03, 2008 | | | | |
| | >A> 5045321*PED | Mar 03, 2009 | | | | |
| | >A> 5093132 | Sep 03, 2008 | | | | |
| | >A> 5093132*PED | Mar 03, 2009 | | | | |
| | >A> 5433959 | Sep 03, 2008 | | | | |
| | >A> 5433959*PED | Mar 03, 2009 | | | | |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
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| | >A> 5013743 | Feb 12, 2010 | U-452 | | | |
| | >A> 5013743*PED | Aug 12, 2010 | | | | |
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| | >A> 5045321 | Sep 03, 2008 | | | | |
| | >A> 5045321*PED | Mar 03, 2009 | | | | |
| | >A> 5093132 | Sep 03, 2008 | | | | |
| | >A> 5093132*PED | Mar 03, 2009 | | | | |
| | >A> 5433959 | Sep 03, 2008 | | | | |
| | >A> 5433959*PED | Mar 03, 2009 | | | | |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 021428 001 | >A> 4628098 | May 10, 2009 | | | | |
| | >A> 4628098*PED | Nov 10, 2009 | | | | |
| | >A> 5013743 | Feb 12, 2010 | U-452 | | | |
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| | >A> 5026560*PED | Dec 25, 2008 | | | | |
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| | >A> 5045321*PED | Mar 03, 2009 | | | | |
| | >A> 5093132 | Sep 03, 2008 | | | | |
| | >A> 5093132*PED | Mar 03, 2009 | | | | |
| | >A> 5433959 | Sep 03, 2008 | | | | |
| | >A> 5433959*PED | Mar 03, 2009 | | | | |
| | >A> 5464632 | Nov 07, 2012 | | | | |
| | >A> 5464632*PED | May 07, 2013 | | | | |
| | >A> 6328994 | May 17, 2019 | | | | |
| | >A> 6328994*PED | Nov 17, 2019 | | | | |

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| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | | |
| 021428 002 | >A> 4628098 | May | 10, 2009 | | | | |
| | >A> 4628098*PED | Nov | 10, 2009 | | | | |
| | >A> 5013743 | Feb | 12, 2010 | U-452 | | | |
| | >A> 5013743*PED | Aug | 12, 2010 | | | | |
| | >A> 5026560 | Jun | 25, 2008 | | | | |
| | >A> 5026560*PED | Dec | 25, 2008 | | | | |
| | >A> 5045321 | Sep | 03, 2008 | | | | |
| | >A> 5045321*PED | Mar | 03, 2009 | | | | |
| | >A> 5093132 | Sep | 03, 2008 | | | | |
| | >A> 5093132*PED | Mar | 03, 2009 | | | | |
| | >A> 5433959 | Sep | 03, 2008 | | | | |
| | >A> 5433959*PED | Mar | 03, 2009 | | | | |
| | >A> 5464632 | Nov | 07, 2012 | | | | |
| | >A> 5464632*PED | May | 07, 2013 | | | | |
| | >A> 6328994 | May | 17, 2019 | | | | |
| | >A> 6328994*PED | Nov | 17, 2019 | | | | |
| <u>LATANOPROST - XALATAN</u> | | | | | | | |
| 020597 001 | 5422368 | Mar | 22, 2011 | DP | U-778 | Y | |
| <u>LENALIDOMIDE - REVLIMID</u> | | | | | | | |
| 021880 001 | 5635517 | Oct | 04, 2019 | DS | U-866 | | |
| <u>LENALIDOMIDE - REVLIMID</u> | | | | | | | |
| 021880 002 | 5635517 | Oct | 04, 2019 | DS | U-866 | | |
| <u>LENALIDOMIDE - REVLIMID</u> | | | | | | | |
| 021880 003 | 5635517 | Oct | 04, 2019 | DS | U-866 | | |
| <u>LENALIDOMIDE - REVLIMID</u> | | | | | | | |
| 021880 004 | 5635517 | Oct | 04, 2019 | DS | U-866 | | |
| <u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u> | | | | | | | |
| 020837 001 | 5362755 | Mar | 25, 2013 | | U-332 | | |
| <u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u> | | | | | | | |
| 020837 002 | 5362755 | Mar | 25, 2013 | | U-332 | | |
| <u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u> | | | | | | | |
| 020837 003 | 5362755 | Mar | 25, 2013 | | U-332 | | |
| <u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u> | | | | | | | |
| 020837 004 | 5362755 | Mar | 25, 2013 | | U-332 | | |
| <u>LEVETIRACETAM - KEPPTRA</u> | | | | | | | |
| 021035 001 | 4943639 | Jul | 14, 2008 | DS | | PED | Sep 19, 2010 |
| | 4943639*PED | Jan | 14, 2009 | | | PED | Feb 15, 2010 |
| | | | | | | PED | Dec 21, 2008 |
| <u>LEVETIRACETAM - KEPPTRA</u> | | | | | | | |
| 021035 002 | 4943639 | Jul | 14, 2008 | DS | | I-527 | Mar 19, 2010 |
| | 4943639*PED | Jan | 14, 2009 | | | I-506 | Aug 15, 2009 |
| | | | | | | NPP | Jun 21, 2008 |
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| | | | | | | PED | Dec 21, 2008 |

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| | 4943639*PED | Jan 14, 2009 | | | I-506 | Aug 15, 2009 |
| | | | | | NPP | Jun 21, 2008 |
| | | | | | PED | Sep 19, 2010 |
| | | | | | PED | Feb 15, 2010 |
| | | | | | PED | Dec 21, 2008 |
| <u>LEVETIRACETAM - KEPPTRA</u> | | | | | | |
| 021035 004 | 4943639 | Jul 14, 2008 | DS | | I-527 | Mar 19, 2010 |
| | 4943639*PED | Jan 14, 2009 | | | I-506 | Aug 15, 2009 |
| | | | | | NPP | Jun 21, 2008 |
| | | | | | PED | Sep 19, 2010 |
| | | | | | PED | Feb 15, 2010 |
| | | | | | PED | Dec 21, 2008 |
| <u>LEVETIRACETAM - KEPPTRA</u> | | | | | | |
| 021505 001 | 4943639 | Jul 14, 2008 | DS | | I-527 | Mar 19, 2010 |
| | 4943639*PED | Jan 14, 2009 | | | I-506 | Aug 15, 2009 |
| | | | | | NPP | Jun 21, 2008 |
| | | | | | PED | Sep 19, 2010 |
| | | | | | PED | Feb 15, 2010 |
| | | | | | PED | Dec 21, 2008 |
| <u>LEVETIRACETAM - KEPPTRA</u> | | | | | | |
| 021872 001 | 4943639 | Jul 14, 2008 | DS | | >A> I-563 | Mar 19, 2010 |
| | 4943639*PED | Jan 14, 2009 | | | I-544 | Aug 15, 2009 |
| | | | | | NDF | Jul 31, 2009 |
| | | | | | PED | Feb 15, 2010 |
| | | | | | PED | Jan 31, 2010 |
| <u>LEVOCETIRIZINE DIHYDROCHLORIDE - XYZAL</u> | | | | | | |
| 022157 001 | 5698558 | Sep 24, 2012 | | U-852 | NP | May 25, 2010 |
| <u>LEVOLEUCOVORIN CALCIUM - LEVOLEUCOVORIN</u> | | | | | | |
| 020140 001 | 6500829 | Dec 31, 2019 | DS DP | | NP | Mar 07, 2011 |
| | | | | | ODE | Mar 07, 2015 |
| <u>LISDEXAMFETAMINE Dimesylate - VYVANSE</u> | | | | | | |
| 021977 001 | | | | | NPP | Apr 23, 2011 |
| <u>LISDEXAMFETAMINE Dimesylate - VYVANSE</u> | | | | | | |
| 021977 002 | | | | | NPP | Apr 23, 2011 |
| <u>LISDEXAMFETAMINE Dimesylate - VYVANSE</u> | | | | | | |
| 021977 003 | | | | | NPP | Apr 23, 2011 |
| <u>LISDEXAMFETAMINE Dimesylate - VYVANSE</u> | | | | | | |
| 021977 004 | 7105486 | Jun 29, 2023 | | U-842 | NPP | Apr 23, 2011 |
| | 7223735 | Jun 29, 2023 | DP | | | |
| <u>LISDEXAMFETAMINE Dimesylate - VYVANSE</u> | | | | | | |
| 021977 005 | 7105486 | Jun 29, 2023 | | U-842 | NPP | Apr 23, 2011 |
| | 7223735 | Jun 29, 2023 | DP | | | |
| <u>LISDEXAMFETAMINE Dimesylate - VYVANSE</u> | | | | | | |
| 021977 006 | 7105486 | Jun 29, 2023 | | U-842 | NPP | Apr 23, 2011 |
| | 7223735 | Jun 29, 2023 | DP | | | |
| <u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - IMODIUM MULTI-SYMPTOM RELIEF</u> | | | | | | |
| 020606 001 | 5248505 | Jul 28, 2010 | | | Y | |
| | 5612054 | Sep 28, 2010 | | | Y | |
| | 5679376 | Oct 21, 2014 | | | Y | |
| | 5716641 | May 21, 2012 | U-226 | | Y | |

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|---------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>LOPINAVIR; RITONAVIR - KALETRA</u> | | | | | | |
| 021226 001 | 5914332 | Dec 13, 2015 | U-351 | | | |
| | 5914332*PED | Jun 13, 2016 | | | | |
| | 6284767 | Feb 15, 2016 | U-401 | | | |
| | 6284767*PED | Aug 15, 2016 | | | | |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u> | | | | | | |
| 021251 001 | 5914332 | Dec 13, 2015 | U-351 | | | |
| | 5914332*PED | Jun 13, 2016 | | | | |
| | 6284767 | Feb 15, 2016 | U-401 | | | |
| | 6284767*PED | Aug 15, 2016 | | | | |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u> | | | | | | |
| 021906 001 | 5914332 | Dec 13, 2015 | DS DP U-688 | | | |
| | 5914332*PED | Jun 13, 2016 | | | | |
| | 6284767 | Feb 15, 2016 | DP U-688 | | | |
| | 6284767*PED | Aug 15, 2016 | | | | |
| | 7148359 | Jul 19, 2019 | DP | | | |
| | 7148359*PED | Jan 19, 2020 | | | | |
| | 7364752 | Nov 10, 2020 | DP U-688 | | | |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u> | | | | | | |
| 021906 002 | 5541206 | Jul 30, 2013 | DS DP U-688 | | | |
| | 5541206*PED | Jan 30, 2014 | | | | |
| | 5635523 | Jun 03, 2014 | U-688 | | | |
| | 5635523*PED | Dec 03, 2014 | | | | |
| | 5648497 | Jul 15, 2014 | DS DP | | | |
| | 5648497*PED | Jan 15, 2015 | | | | |
| | 5674882 | Oct 07, 2014 | U-688 | | | |
| | 5674882*PED | Apr 07, 2015 | | | | |
| | 5846987 | Dec 29, 2012 | U-688 | | | |
| | 5846987*PED | Jun 29, 2013 | | | | |
| | 5886036 | Nov 19, 2013 | DS DP | | | |
| | 5886036*PED | May 19, 2014 | | | | |
| | 5914332 | Dec 13, 2015 | DS DP U-688 | | | |
| | 5914332*PED | Jun 13, 2016 | | | | |
| | 6037157 | Jun 26, 2016 | U-688 | | | |
| | 6037157*PED | Dec 26, 2016 | | | | |
| | 6284767 | Feb 15, 2016 | DP U-688 | | | |
| | 6284767*PED | Aug 15, 2016 | | | | |
| | 6703403 | Jun 26, 2016 | U-688 | | | |
| | 6703403*PED | Dec 26, 2016 | | | | |
| | 7148359 | Jul 19, 2019 | DP | | | |
| | 7148359*PED | Jan 19, 2020 | | | | |
| | 7364752 | Nov 10, 2020 | DP U-688 | | | |
| <u>LOSARTAN POTASSIUM - COZAAR</u> | | | | | | |
| 020386 001 | 5608075 | Mar 04, 2014 | | Y | | |
| <u>LOSARTAN POTASSIUM - COZAAR</u> | | | | | | |
| 020386 002 | 5608075 | Mar 04, 2014 | | Y | | |
| <u>LOSARTAN POTASSIUM - COZAAR</u> | | | | | | |
| 020386 003 | 5608075 | Mar 04, 2014 | | Y | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>LUBIPROSTONE - AMITIZA</u> | | | | | | |
| 021908 001 | 5284858 | Jul 14, 2014 | DS DP | | | |
| <u>LUBIPROSTONE - AMITIZA</u> | | | | | | |
| 021908 002 | 5284858 | Jul 14, 2014 | DS DP | I-557 | Apr 28, 2011 | |
| | 5317032 | May 31, 2011 | DS DP U-874 | NS | Apr 28, 2011 | |
| | 6414016 | Sep 05, 2020 | DS DP U-874 | NCE | Jan 31, 2011 | |
| | 6583174 | Oct 16, 2020 | DS DP | | | |
| | 7064148 | Aug 30, 2022 | DS DP U-873 | | | |
| <u>MAGNESIUM HYDROXIDE; OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u> | | | | | | |
| 021850 001 | >A> 7399772 | Jul 16, 2016 | U-588 | | | |
| <u>MAGNESIUM HYDROXIDE; OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u> | | | | | | |
| 021850 002 | >A> 7399772 | Jul 16, 2016 | U-623 | | | |
| <u>MARAVIROC - SELZENTRY</u> | | | | | | |
| 022128 001 | 7368460 | Nov 25, 2022 | U-824 | | | |
| <u>MARAVIROC - SELZENTRY</u> | | | | | | |
| 022128 002 | 7368460 | Nov 25, 2022 | U-824 | | | |
| <u>MENTHOL; METHYL SALICYLATE - SALONPAS</u> | | | | | | |
| 022029 001 | | | | NDF | Feb 20, 2011 | |
| | | | | NC | Feb 20, 2011 | |
| <u>MESALAMINE - MESALAMINE</u> | | | | | | |
| 021830 001 | >A> 5541170 | Jul 30, 2013 | DP U-141 | NP | May 29, 2011 | |
| | >A> 5541171 | Jul 30, 2013 | DP U-141 | | | |
| | >A> 6893662 | Nov 15, 2021 | DP U-141 | | | |
| <u>METFORMIN HYDROCHLORIDE - GLUMETZA</u> | | | | | | |
| 021748 001 | >A> 6635280 | Sep 19, 2016 | DS DP | | | |
| <u>METFORMIN HYDROCHLORIDE - GLUMETZA</u> | | | | | | |
| 021748 002 | >A> 6635280 | Sep 19, 2016 | DS DP | | | |
| <u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u> | | | | | | |
| 021410 001 | 5741803 | Apr 21, 2015 | DS DP U-734 | Y | | |
| | 5741803 | Apr 21, 2015 | DS DP U-493 | Y | | |
| | 5965584 | Jun 19, 2016 | U-493 | Y | | |
| | 6166042 | Jun 19, 2016 | U-493 | Y | | |
| | 6288095 | Feb 11, 2017 | U-493 | Y | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u> | | | | | | |
| 021410 002 | 5741803 | Apr 21, 2015 | DS DP U-734 | Y | | |
| | 5741803 | Apr 21, 2015 | DS DP U-493 | Y | | |
| | 5965584 | Jun 19, 2016 | U-493 | Y | | |
| | 6166042 | Jun 19, 2016 | U-493 | Y | | |
| | 6288095 | Feb 11, 2017 | U-493 | Y | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |

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|---|-------------|------------------------------|----------|-----------------|-------------------------------|------------------------------|-----------------------------------|
| <u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u> | | | | | | | |
| 021410 003 | 5741803 | Apr | 21, 2015 | DS DP U-734 | Y | | |
| | 5741803 | Apr | 21, 2015 | DS DP U-493 | Y | | |
| | 5965584 | Jun | 19, 2016 | U-493 | Y | | |
| | 6166042 | Jun | 19, 2016 | U-493 | Y | | |
| | 6288095 | Feb | 11, 2017 | U-493 | Y | | |
| | 7358366 | Apr | 19, 2020 | DS | | | |
| | 7358366*PED | Oct | 19, 2020 | | | | |
| <u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u> | | | | | | | |
| 021410 004 | 5741803 | Apr | 21, 2015 | DS DP U-734 | Y | | |
| | 5741803 | Apr | 21, 2015 | DS DP U-493 | Y | | |
| | 7358366 | Apr | 19, 2020 | DS | | | |
| | 7358366*PED | Oct | 19, 2020 | | | | |
| <u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u> | | | | | | | |
| 021410 005 | 5741803 | Apr | 21, 2015 | DS DP U-734 | Y | | |
| | 5741803 | Apr | 21, 2015 | DS DP U-493 | Y | | |
| | 7358366 | Apr | 19, 2020 | DS | | | |
| | 7358366*PED | Oct | 19, 2020 | | | | |
| <u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u> | | | | | | | |
| 022044 001 | 7326708 | Apr | 11, 2026 | DS DP U-802 | M-69 M-68 | Oct 12, 2010 Oct 12, 2010 | |
| <u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u> | | | | | | | |
| 022044 002 | 7326708 | Apr | 11, 2026 | DS DP U-802 | M-69 M-68 | Oct 12, 2010 Oct 12, 2010 | |
| <u>METHYLNALTREXONE BROMIDE - RELISTOR</u> | | | | | | | |
| 021964 001 | | | | | NCE | Apr 24, 2013 | |
| <u>MICAFUNGIN SODIUM - MYCAMEINE</u> | | | | | | | |
| 021506 002 | 6107458 | Mar | 16, 2019 | DS DP U-845 | I-554 | Jan 22, 2011 | |
| | 6107458 | Mar | 16, 2019 | DS DP U-650 | | | |
| | 6265536 | Sep | 29, 2015 | DS DP U-845 | | | |
| | 6265536 | Sep | 29, 2015 | DS DP U-650 | | | |
| | 6774104 | Jan | 08, 2021 | DP U-845 | | | |
| | 6774104 | Jan | 08, 2021 | DP U-650 | | | |
| <u>MICAFUNGIN SODIUM - MYCAMEINE</u> | | | | | | | |
| 021506 003 | 5376634 | Dec | 27, 2011 | DS DP | I-554 | Jan 22, 2011 | |
| | 6107458 | Mar | 16, 2019 | DS DP U-845 | NCE | Mar 16, 2010 | |
| | 6107458 | Mar | 16, 2019 | DS DP U-650 | | | |
| | 6265536 | Sep | 29, 2015 | DS DP U-845 | | | |
| | 6265536 | Sep | 29, 2015 | DS DP U-650 | | | |
| | 6774104 | Jan | 08, 2021 | DP U-845 | | | |
| | 6774104 | Jan | 08, 2021 | DP U-650 | | | |
| <u>MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION</u> | | | | | | | |
| 021026 001 | 4911932 | Mar | 27, 2009 | DP U-718 | | | |
| <u>MODAFINIL - PROVIGIL</u> | | | | | | | |
| 020717 001 | 7297346 | Nov | 29, 2023 | DP | | | |
| <u>MODAFINIL - PROVIGIL</u> | | | | | | | |
| 020717 002 | 7297346 | Nov | 29, 2023 | DP | | | |

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|--|------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>MOMETASONE FUROATE - ASMANEX TWISTHALER</u> | | | | | | |
| | 021067 001 | | | | NPP | Feb 01, 2011 |
| <u>NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE - TREXIMET</u> | | | | | | |
| 021926 001 | 5037845 | Aug 06, 2008 | DS DP U-867 | | | |
| | 6060499 | Aug 14, 2017 | DP U-867 | | | |
| | 6586458 | Aug 14, 2017 | DP U-867 | | | |
| | 7332183 | Oct 02, 2025 | DP U-867 | | | |
| <u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u> | | | | | | |
| 021742 002 | 5759580 | Jun 02, 2015 | DP | | | |
| | 6545040 | Apr 08, 2020 | DP U-3 | | | |
| <u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u> | | | | | | |
| 021742 003 | 5759580 | Jun 02, 2015 | DP | | | |
| | 6545040 | Apr 08, 2020 | DP U-3 | | | |
| <u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u> | | | | | | |
| 021742 004 | 5759580 | Jun 02, 2015 | DP | | | |
| | 6545040 | Apr 08, 2020 | DP U-3 | | | |
| <u>NESIRITIDE RECOMBINANT - NATRECOR</u> | | | | | | |
| 020920 001 | 5114923 | May 19, 2014 | DS DP U-855 | | | |
| <u>NIACIN; SIMVASTATIN - SIMCOR</u> | | | | | | |
| 022078 001 | 6080428 | May 27, 2017 | U-862 | | NC | Feb 15, 2011 |
| | 6129930 | Sep 20, 2013 | DP U-862 | | | |
| | 6406715 | Sep 20, 2013 | DP | | | |
| | 6469035 | Mar 15, 2018 | U-863 | | | |
| | 6676967 | Sep 20, 2013 | U-862 | | | |
| | 6746691 | Sep 20, 2013 | DP | | | |
| | 6818229 | Feb 15, 2014 | DP | | | |
| | 7011848 | Sep 20, 2013 | U-862 | | | |
| <u>NIACIN; SIMVASTATIN - SIMCOR</u> | | | | | | |
| 022078 002 | 6080428 | May 27, 2017 | U-862 | | NC | Feb 15, 2011 |
| | 6129930 | Sep 20, 2013 | DP U-862 | | | |
| | 6406715 | Sep 20, 2013 | DP | | | |
| | 6469035 | Mar 15, 2018 | U-863 | | | |
| | 6676967 | Sep 20, 2013 | U-862 | | | |
| | 6746691 | Sep 20, 2013 | DP | | | |
| | 6818229 | Feb 15, 2014 | DP | | | |
| | 7011848 | Sep 20, 2013 | U-862 | | | |
| <u>NIACIN; SIMVASTATIN - SIMCOR</u> | | | | | | |
| 022078 003 | 6080428 | May 27, 2017 | U-862 | | NC | Feb 15, 2011 |
| | 6129930 | Sep 20, 2013 | DP U-862 | | | |
| | 6406715 | Sep 20, 2013 | DP | | | |
| | 6469035 | Mar 15, 2018 | U-863 | | | |
| | 6676967 | Sep 20, 2013 | U-862 | | | |
| | 6746691 | Sep 20, 2013 | DP | | | |
| | 6818229 | Feb 15, 2014 | DP | | | |
| | 7011848 | Sep 20, 2013 | U-862 | | | |
| <u>NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA</u> | | | | | | |
| 022068 001 | | | | | ODE | Oct 29, 2014 |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>NISOLDIPINE - SULAR</u> | | | | | | |
| 020356 005 | 5422123 | Jun 06, 2012 | DP | | | |
| | 5626874 | Nov 30, 2014 | DP | | | |
| <u>NISOLDIPINE - SULAR</u> | | | | | | |
| 020356 006 | 5422123 | Jun 06, 2012 | DP | | | |
| | 5626874 | Nov 30, 2014 | DP | | | |
| <u>NISOLDIPINE - SULAR</u> | | | | | | |
| 020356 007 | 5422123 | Jun 06, 2012 | DP | | | |
| | 5626874 | Nov 30, 2014 | DP | | | |
| <u>NISOLDIPINE - SULAR</u> | | | | | | |
| 020356 008 | 5422123 | Jun 06, 2012 | DP | | | |
| | 5626874 | Nov 30, 2014 | DP | | | |
| <u>NITROGLYCERIN - NITROLINGUAL PUMPSPRAY</u> | | | | | | |
| 018705 002 | >A> 5186925 | Mar 06, 2011 | DP | | | |
| <u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u> | | | | | | |
| 021008 001 | | | | | M-73 | Mar 03, 2011 |
| <u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u> | | | | | | |
| 021008 002 | | | | | M-73 | Mar 03, 2011 |
| <u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u> | | | | | | |
| 021008 003 | | | | | M-73 | Mar 03, 2011 |
| <u>OLMESARTAN MEDOXOMIL - BENICAR</u> | | | | | | |
| 021286 001 | 6878703 | Nov 19, 2021 | U-3 | Y | | |
| <u>OLMESARTAN MEDOXOMIL - BENICAR</u> | | | | | | |
| 021286 003 | 6878703 | Nov 19, 2021 | U-3 | Y | | |
| <u>OLMESARTAN MEDOXOMIL - BENICAR</u> | | | | | | |
| 021286 004 | 6878703 | Nov 19, 2021 | U-3 | Y | | |
| <u>OLOPATADINE HYDROCHLORIDE - PATANASE</u> | | | | | | |
| 021861 001 | 5116863 | Dec 18, 2010 | DS DP | | NDF | Apr 15, 2011 |
| <u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u> | | | | | | |
| 022056 001 | 5690960 | Nov 25, 2014 | DP U-864 | | NPP | Mar 20, 2011 |
| | 5900424 | May 04, 2016 | DS U-864 | | PED | Sep 20, 2011 |
| | 6428810 | Nov 03, 2019 | DP U-864 | | | |
| <u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u> | | | | | | |
| 022056 002 | 5690960 | Nov 25, 2014 | DP U-864 | | NPP | Mar 20, 2011 |
| | 5900424 | May 04, 2016 | DS U-864 | | PED | Sep 20, 2011 |
| | 6428810 | Nov 03, 2019 | DP U-864 | | | |
| <u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u> | | | | | | |
| 021636 001 | >A> 7399772 | Jul 16, 2016 | U-588 | | | |
| <u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u> | | | | | | |
| 021636 002 | >A> 7399772 | Jul 16, 2016 | U-624 | | | |
| | >A> 7399772 | Jul 16, 2016 | U-623 | | | |
| <u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u> | | | | | | |
| 021849 001 | >A> 7399772 | Jul 16, 2016 | U-588 | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|--|-----------------------------------|
| <u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u> | | | | | | |
| 021849 002 | >A> 7399772 | Jul 16, 2016 | U-623 | | | |
| <u>OXCARBAZEPINE - OXCARBAZEPINE</u> | | | | | | |
| | 078069 001 | | | | PC | Apr 06, 2008 |
| <u>OXCARBAZEPINE - OXCARBAZEPINE</u> | | | | | | |
| | 078069 002 | | | | PC | Apr 06, 2008 |
| <u>OXCARBAZEPINE - OXCARBAZEPINE</u> | | | | | | |
| | 078069 003 | | | | PC | Apr 06, 2008 |
| <u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u> | | | | | | |
| 021610 005 | 5128143 | Sep 19, 2008 | DP | | NDF | Jun 22, 2009 |
| | 5662933 | Sep 09, 2013 | DP | | | |
| | 5958456 | Sep 09, 2013 | DP | | | |
| | 7276250 | Jul 03, 2022 | DP U-826 | | | |
| <u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u> | | | | | | |
| 021610 006 | 5128143 | Sep 19, 2008 | DP | | NDF | Jun 22, 2009 |
| | 5662933 | Sep 09, 2013 | DP | | | |
| | 5958456 | Sep 09, 2013 | DP | | | |
| | 7276250 | Jul 03, 2022 | DP U-826 | | | |
| <u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u> | | | | | | |
| 021610 007 | 5128143 | Sep 19, 2008 | DP | | NDF | Jun 22, 2009 |
| | 5662933 | Sep 09, 2013 | DP | | | |
| | 5958456 | Sep 09, 2013 | DP | | | |
| | 7276250 | Jul 03, 2022 | DP U-826 | | | |
| <u>PALONOSETRON HYDROCHLORIDE - ALOXI</u> | | | | | | |
| 021372 002 | | | | I-556 NS NCE | Mar 01, 2011 Mar 01, 2011 Jul 25, 2008 | |
| <u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u> | | | | | | |
| 077056 001 | | | | PC | Jun 18, 2008 | |
| <u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u> | | | | | | |
| 077056 002 | | | | PC | Jun 18, 2008 | |
| <u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u> | | | | | | |
| 077058 001 | | | | PC | Jun 18, 2008 | |
| <u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u> | | | | | | |
| 077058 002 | | | | PC | Jun 18, 2008 | |
| <u>PANTOPRAZOLE SODIUM - PROTONIX</u> | | | | | | |
| 022020 001 | 4758579 | Jul 19, 2010 | DS DP U-859 | | | |
| <u>PANTOPRAZOLE SODIUM - PROTONIX IV</u> | | | | | | |
| 020988 001 | 7351723 | Nov 17, 2021 | DP | | | |
| <u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u> | | | | | | |
| 077873 001 | | | | PC | Nov 10, 2008 | |
| <u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u> | | | | | | |
| 077873 002 | | | | PC | Nov 10, 2008 | |
| <u>PEGAPTANIB SODIUM - MACUGEN</u> | | | | | | |
| 021756 001 | 6051698 | May 19, 2015 | DS | U-622 | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>PEGVISOMANT - SOMAVERT</u> | | | | | | |
| 021106 001 | >A> 5849535 | Mar 25, 2017 | DS | | | |
| <u>PEGVISOMANT - SOMAVERT</u> | | | | | | |
| 021106 002 | >A> 5849535 | Mar 25, 2017 | DS | | | |
| <u>PEGVISOMANT - SOMAVERT</u> | | | | | | |
| 021106 003 | >A> 5849535 | Mar 25, 2017 | DS | | | |
| <u>PEMETREXED DISODIUM - ALIMTA</u> | | | | | | |
| 021462 002 | 5217974 | Mar 29, 2011 | | U-551 | | |
| <u>PHENTOLAMINE MESYLATE - ORAVERSE</u> | | | | | | |
| 022159 001 | | | | | NP | May 09, 2011 |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 001 | 4886812 | Oct 08, 2010 | DS DP | | | |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 002 | 4886812 | Oct 08, 2010 | DS DP | | | |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 003 | 4886812 | Oct 08, 2010 | DS DP | | | |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 004 | 4886812 | Oct 08, 2010 | DS DP | | | |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 005 | 4886812 | Oct 08, 2010 | DS DP | | | |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 006 | 4886812 | Oct 08, 2010 | DS DP | | | |
| <u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u> | | | | | | |
| 020667 007 | 4886812 | Oct 08, 2010 | DS DP | | I-517 | Nov 07, 2009 |
| | 6001861 | Jan 16, 2018 | | U-784 | | |
| | 6194445 | Jan 16, 2018 | | U-784 | | |
| <u>PRAMLINTIDE ACETATE - SYMLIN</u> | | | | | | |
| 021332 001 | 5686411 | Mar 16, 2019 | DS DP | U-638 | | |
| | 7271238 | Mar 08, 2011 | DS | U-638 | | |
| | 7271238 | Mar 08, 2011 | DS | U-637 | | |
| <u>PRAMLINTIDE ACETATE - SYMLIN</u> | | | | | | |
| 021332 002 | 5686411 | Mar 16, 2019 | DS DP | U-638 | | |
| | 7271238 | Mar 08, 2011 | DS | U-638 | | |
| | 7271238 | Mar 08, 2011 | DS | U-637 | | |
| <u>PRAMLINTIDE ACETATE - SYMLIN</u> | | | | | | |
| 021332 003 | 5686411 | Mar 16, 2019 | DS DP | U-638 | | |
| | 7271238 | Mar 08, 2011 | DS | U-638 | | |
| | 7271238 | Mar 08, 2011 | DS | U-637 | | |
| <u>PREDNISOLONE ACETATE - FLO-PRED</u> | | | | | | |
| 022067 001 | 5881926 | Mar 16, 2016 | | DP | | |
| | 6071523 | Jun 03, 2018 | | DP | | |
| | 6102254 | Mar 11, 2013 | | DP | | |
| | 6399079 | Jun 03, 2018 | | DP | | |
| | 6656482 | Jun 03, 2018 | | DP | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>PREDNISOLONE ACETATE - FLO-PRED</u> | | | | | | |
| 022067 002 | 5881926 | Mar 16, 2016 | DP | | | |
| | 6071523 | Jun 03, 2018 | DP | | | |
| | 6102254 | Mar 11, 2013 | DP | | | |
| | 6399079 | Jun 03, 2018 | DP | | | |
| | 6656482 | Jun 03, 2018 | DP | | | |
| <u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u> | | | | | | |
| 021959 001 | 6024981 | Apr 09, 2018 | DP | | | |
| | 6221392 | Apr 09, 2018 | DP | | | |
| <u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u> | | | | | | |
| 021959 002 | 6024981 | Apr 09, 2018 | DP | | | |
| | 6221392 | Apr 09, 2018 | DP | | | |
| <u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u> | | | | | | |
| 021959 003 | 6024981 | Apr 09, 2018 | DP | | | |
| | 6221392 | Apr 09, 2018 | DP | | | |
| <u>PROGESTERONE - ENDOMETRIN</u> | | | | | | |
| 022057 001 | 7300664 | Nov 17, 2019 | U-856 | | | |
| | 7320800 | Nov 17, 2019 | U-856 | | | |
| | >A> 7393543 | Nov 17, 2019 | DP U-880 | | | |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 001 | | | | I-560 | | May 13, 2011 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 002 | | | | I-560 | | May 13, 2011 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 003 | | | | I-560 | | May 13, 2011 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 004 | | | | I-560 | | May 13, 2011 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 005 | | | | I-560 | | May 13, 2011 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 006 | | | | I-560 | | May 13, 2011 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 007 | | | | I-560 | | May 13, 2011 |
| <u>RABEPRAZOLE SODIUM - ACIPHEX</u> | | | | | | |
| 020973 002 | | | | >A> NPP | | Jun 30, 2011 |
| <u>RALOXIFENE HYDROCHLORIDE - EVISTA</u> | | | | | | |
| 020815 001 | 5393763 | Jul 28, 2012 | U-114 | Y | ODE | Sep 13, 2014 |
| | 5457117 | Jul 28, 2012 | U-114 | Y | | |
| | 5478847 | Mar 02, 2014 | U-114 | Y | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 019901 001 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 019901 002 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 019901 003 | 7368469 | Aug 30, 2020 | U-871 | | | |

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| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 019901 004 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 022021 001 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 022021 002 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 022021 003 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - ALTACE</u> | | | | | | |
| 022021 004 | 7368469 | Aug 30, 2020 | U-871 | | | |
| <u>RAMIPRIL - RAMIPRIL</u> | | | | | | |
| 077626 001 | | | | >A> PC | | Dec 07, 2008 |
| <u>RAMIPRIL - RAMIPRIL</u> | | | | | | |
| 077626 002 | | | | >A> PC | | Dec 07, 2008 |
| <u>RAMIPRIL - RAMIPRIL</u> | | | | | | |
| 077626 003 | | | | >A> PC | | Dec 07, 2008 |
| <u>RAMIPRIL - RAMIPRIL</u> | | | | | | |
| 077626 004 | | | | >A> PC | | Dec 07, 2008 |
| <u>REGADENOSON - LEXISCAN</u> | | | | | | |
| 022161 001 | 6403567 | Jun 22, 2019 | DS DP U-869 | | NCE | Apr 10, 2013 |
| | 6642210 | Jun 22, 2019 | DS DP U-869 | | | |
| | 7144872 | Jun 22, 2019 | DS DP U-870 | | | |
| | 7144872 | Jun 22, 2019 | DS DP U-869 | | | |
| | 7144872 | Jun 22, 2019 | DS DP U-116 | | | |
| | 7183264 | Jun 22, 2019 | DP U-870 | | | |
| | 7183264 | Jun 22, 2019 | DP U-869 | | | |
| | 7183264 | Jun 22, 2019 | DP U-116 | | | |
| <u>RISEDRONATE SODIUM - ACTONEL</u> | | | | | | |
| 020835 005 | 5583122 | Dec 10, 2013 | DS DP U-353 | | M-52 | Jan 24, 2009 |
| | 6165513 | Jun 10, 2018 | DP | | | |
| | 7192938 | May 06, 2023 | U-353 | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 001 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 002 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 003 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 004 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 005 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 007 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020272 008 | 5158952 | Oct 27, 2009 | U-90 | Y | | |
| | 5158952*PED | Apr 27, 2010 | | | | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | | |
| 020588 001 | 5616587 | Jul 11, 2014 | | Y | | |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076228 001 | | | | >A> PC | | Dec 27, 2008 |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076228 002 | | | | >A> PC | | Dec 27, 2008 |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076228 003 | | | | >A> PC | | Dec 27, 2008 |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076228 004 | | | | >A> PC | | Dec 27, 2008 |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076228 005 | | | | >A> PC | | Dec 27, 2008 |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076228 006 | | | | >A> PC | | Dec 27, 2008 |
| <u>ROCURONIUM BROMIDE - ZEMURON</u> | | | | | | |
| 020214 001 | 4894369 | Apr 13, 2008 | | | | |
| | 4894369*PED | Oct 13, 2008 | | | | |
| <u>ROCURONIUM BROMIDE - ZEMURON</u> | | | | | | |
| 020214 002 | 4894369 | Apr 13, 2008 | | | | |
| | 4894369*PED | Oct 13, 2008 | | | | |
| <u>ROCURONIUM BROMIDE - ZEMURON</u> | | | | | | |
| 020214 003 | 4894369 | Apr 13, 2008 | | | | |
| | 4894369*PED | Oct 13, 2008 | | | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP XL</u> | | | | | | |
| 022008 001 | >A> 5422123 | Jun 06, 2012 | DP | | >A> NDF | Jun 13, 2011 |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP XL</u> | | | | | | |
| 022008 002 | >A> 5422123 | Jun 06, 2012 | DP | | >A> NDF | Jun 13, 2011 |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP XL</u> | | | | | | |
| 022008 003 | >A> 5422123 | Jun 06, 2012 | DP | | >A> NDF | Jun 13, 2011 |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP XL</u> | | | | | | |
| 022008 004 | >A> 5422123 | Jun 06, 2012 | DP | | >A> NDF | Jun 13, 2011 |

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| <u>ROSIGLITAZONE MALEATE - AVANDIA</u> | | | | | | |
| 021071 002 | 5741803 | Apr 21, 2015 | DS DP U-628 | Y | | |
| | 5741803 | Apr 21, 2015 | DS DP U-329 | Y | | |
| | 6288095 | Feb 11, 2017 | U-420 | Y | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>ROSIGLITAZONE MALEATE - AVANDIA</u> | | | | | | |
| 021071 003 | 5741803 | Apr 21, 2015 | DS DP U-628 | Y | | |
| | 5741803 | Apr 21, 2015 | DS DP U-329 | Y | | |
| | 6288095 | Feb 11, 2017 | U-420 | Y | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>ROSIGLITAZONE MALEATE - AVANDIA</u> | | | | | | |
| 021071 004 | 5741803 | Apr 21, 2015 | DS DP U-628 | Y | | |
| | 5741803 | Apr 21, 2015 | DS DP U-329 | Y | | |
| | 6288095 | Feb 11, 2017 | U-420 | Y | | |
| | 7358366 | Apr 19, 2020 | DS | | | |
| | 7358366*PED | Oct 19, 2020 | | | | |
| <u>SEVELAMER CARBONATE - RENVELA</u> | | | | | | |
| 022127 001 | 5496545 | Aug 11, 2013 | DP U-246 | | | |
| | 5667775 | Sep 16, 2014 | U-246 | | | |
| | 6509013 | Aug 11, 2013 | DP | | | |
| | 6858203 | Aug 11, 2013 | DP U-246 | | | |
| | 7014846 | Aug 11, 2013 | DP U-246 | | | |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | | |
| 021083 001 | | | | | D-114 | Jan 30, 2010 |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | | |
| 021110 001 | 5145684 | Jan 25, 2011 | DP U-857 | | D-114 | Jan 30, 2010 |
| | 5145684*PED | Jul 25, 2011 | | | | |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | | |
| 021110 002 | 5145684 | Jan 25, 2011 | DP U-857 | | D-114 | Jan 30, 2010 |
| | 5145684*PED | Jul 25, 2011 | | | | |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | | |
| 021110 003 | 5145684 | Jan 25, 2011 | DP U-857 | | | |
| | 5145684*PED | Jul 25, 2011 | | | | |
| <u>SITAGLIPTIN PHOSPHATE - JANUVIA</u> | | | | | | |
| 021995 001 | 7326708 | Apr 11, 2026 | DS DP U-802 | | | |
| <u>SITAGLIPTIN PHOSPHATE - JANUVIA</u> | | | | | | |
| 021995 002 | 7326708 | Apr 11, 2026 | DS DP U-802 | | | |
| <u>SITAGLIPTIN PHOSPHATE - JANUVIA</u> | | | | | | |
| 021995 003 | 7326708 | Apr 11, 2026 | DS DP U-802 | | | |
| <u>SODIUM OXYBATE - XYREM</u> | | | | | | |
| 021196 001 | 6780889 | Jul 04, 2020 | DP | | | |
| | 7262219 | Jul 04, 2020 | DP | | | |

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| <u>SOMATROPIN RECOMBINANT - ACCRETROPIN</u> | | | | | | |
| 021538 001 | | | | | NP | Jan 23, 2011 |
| <u>SOMATROPIN RECOMBINANT - OMNITROPE</u> | | | | | | |
| 021426 003 | | | | | NP | May 30, 2009 |
| <u>SORAFENIB TOSYLATE - NEXAVAR</u> | | | | | | |
| 021923 001 | 7351834 | Jan 12, 2020 | DS | | ODE | Nov 16, 2014 |
| <u>SUMATRIPTAN SUCCINATE - IMITREX</u> | | | | | | |
| 020132 001 | 5863559 | Jan 26, 2016 | U-72 | Y | | |
| | 6020001 | Mar 02, 2012 | U-444 | Y | | |
| | 6368627 | Mar 02, 2012 | U-444 | Y | | |
| <u>SUMATRIPTAN SUCCINATE - IMITREX</u> | | | | | | |
| 020132 002 | 5863559 | Jan 26, 2016 | U-72 | Y | | |
| | 6020001 | Mar 02, 2012 | U-444 | Y | | |
| | 6368627 | Mar 02, 2012 | U-444 | Y | | |
| <u>SUMATRIPTAN SUCCINATE - IMITREX</u> | | | | | | |
| 020132 003 | 5863559 | Jan 26, 2016 | U-72 | Y | | |
| | 6020001 | Mar 02, 2012 | U-444 | Y | | |
| | 6368627 | Mar 02, 2012 | U-444 | Y | | |
| <u>SUMATRIPTAN SUCCINATE - IMITREX STATDOSE</u> | | | | | | |
| 020080 002 | 5037845 | Aug 06, 2008 | DS DP | U-848 | | |
| | 5037845*PED | Feb 06, 2009 | | | | |
| <u>SUNITINIB MALATE - SUTENT</u> | | | | | | |
| 021938 001 | >A> 7211600 | Dec 22, 2020 | | U-883 | | |
| <u>SUNITINIB MALATE - SUTENT</u> | | | | | | |
| 021938 002 | >A> 7211600 | Dec 22, 2020 | | U-883 | | |
| <u>SUNITINIB MALATE - SUTENT</u> | | | | | | |
| 021938 003 | >A> 7211600 | Dec 22, 2020 | | U-883 | | |
| <u>TADALAFIL - CIALIS</u> | | | | | | |
| 021368 001 | | | | | D-111 | Jan 07, 2011 |
| <u>TADALAFIL - CIALIS</u> | | | | | | |
| 021368 004 | 5859006 | Nov 21, 2017 | DS DP | | D-111 | Jan 07, 2011 |
| | 6140329 | Jul 11, 2016 | DP U-155 | | NCE | Nov 21, 2008 |
| | 6821975 | Nov 19, 2020 | DS DP U-614 | | | |
| | 6821975 | Nov 19, 2020 | DS DP U-533 | | | |
| | 6943166 | Apr 26, 2020 | U-155 | | | |
| | 7182958 | Apr 26, 2020 | DP U-155 | | | |
| <u>TECHNETIUM TC-99M SESTAMIBI KIT - CARDIOLITE</u> | | | | | | |
| 019785 001 | 4988827 | Jan 29, 2008 | | | | |
| | 4988827*PED | Jul 29, 2008 | | | | |
| <u>TERBINAFINE - LAMISIL AT</u> | | | | | | |
| 021958 001 | 6121314 | May 18, 2012 | | U-540 | | |
| | 6121314 | May 18, 2012 | | U-504 | | |
| <u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u> | | | | | | |
| 021318 001 | 7351414 | Aug 19, 2019 | | U-865 | | |

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| <u>TESTOSTERONE - TESTIM</u> | | | | | | |
| 021454 001 | 7320968 | Jan 18, 2025 | | U-843 | | |
| <u>TIGECYCLINE - TYGACIL</u> | | | | | | |
| 021821 001 | RE40086 | Jun 25, 2013 | | U-282 | | |
| | RE40183 | Apr 09, 2016 | DS DP | | | |
| <u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u> | | | | | | |
| 021395 001 | 5478578 | Dec 26, 2012 | DP | | | |
| | 7309707 | Mar 10, 2023 | DS DP | | | |
| <u>TIPRANAVIR - APTIVUS</u> | | | | | | |
| 021814 001 | 5852195 | Jun 22, 2019 | DS | | NCE | Jun 22, 2010 |
| | 5852195*PED | Dec 22, 2019 | | | PED | Dec 22, 2010 |
| | 6147095 | Oct 29, 2019 | | U-670 | | |
| | 6147095*PED | Apr 29, 2020 | | | | |
| | 6169181 | May 06, 2014 | DS | | | |
| | 6169181*PED | Nov 06, 2014 | | | | |
| | 6231887 | Jul 27, 2018 | DP | | | |
| | 6231887*PED | Jan 27, 2019 | | | | |
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PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 6 - June 2008

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

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**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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| <u>HYDROXYETHYL STARCH 130/0.4 IN 6% SODIUM CHLORIDE 0.9% - VOLUVEN</u> | | | | NP | Dec 10, 2010 |
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PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 28th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of patent terms is available at
<http://www.accessdata.fda.gov/scripts/cder/ob/docs/patternsall.cfm>